

117TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food and Drug Administration Safety and Landmark
6 Advancements Act of 2022” or the “FDASLA Act of
7 2022”.

8 (b) TABLE OF CONTENTS.—The table of contents for
9 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

2

- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirement.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Accreditation programs.
- Sec. 205. Sunset dates.
- Sec. 206. Effective date.
- Sec. 207. Savings clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL
PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar biological product fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

TITLE V—IMPROVING REGULATION OF DRUGS AND BIOLOGICAL
PRODUCTS

- Sec. 501. Alternatives to animal testing.
- Sec. 502. Safer disposal of opioids.
- Sec. 503. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.
- Sec. 504. Improvements to the Purple Book.

TITLE VI—OTHER REAUTHORIZATIONS

- Sec. 601. Reauthorization of the critical path public-private partnership.
- Sec. 602. Reauthorization of the best pharmaceuticals for children program.
- Sec. 603. Reauthorization of the humanitarian device exemption incentive.
- Sec. 604. Reauthorization of the pediatric device consortia program.
- Sec. 605. Reauthorization of provision pertaining to drugs containing single enantiomers.
- Sec. 606. Reauthorization of orphan drug grants.

TITLE VII—ENHANCING FDA HIRING AUTHORITIES

3

- Sec. 701. Enhancing FDA hiring authority for scientific, technical, and professional personnel.
- Sec. 702. Strategic workforce plan and report.

TITLE VIII—ADVANCING REGULATION OF COSMETICS, DIETARY SUPPLEMENTS, AND LABORATORY DEVELOPED TESTS

Subtitle A—Cosmetics

- Sec. 801. Short title.
- Sec. 802. Amendments to cosmetic requirements.
- Sec. 803. Enforcement and conforming amendments.
- Sec. 804. Records inspection.
- Sec. 805. Talc-containing cosmetics.
- Sec. 806. Funding.

Subtitle B—Dietary Supplements

- Sec. 811. Regulation of dietary supplements.

Subtitle C—In Vitro Clinical Tests

- Sec. 821. Short title; table of contents.
- Sec. 822. Definitions.
- Sec. 823. Regulation of in vitro clinical tests.
- Sec. 824. Enforcement and other provisions.
- Sec. 825. Transition.
- Sec. 826. Emergency use authorization.
- Sec. 827. Antimicrobial susceptibility tests.
- Sec. 828. Combination products.
- Sec. 829. Resources.

TITLE IX—OTHER PROVISIONS

- Sec. 901. Facilities management.
- Sec. 902. Annual report on inspections.
- Sec. 903. User fee program transparency and accountability.

1 **TITLE I—FEES RELATING TO**
2 **DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2022”.

6 (b) **FINDING.**—Congress finds that the fees author-
7 ized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-

1 cluding postmarket drug safety activities, as set forth in
2 the goals identified for purposes of part 2 of subchapter
3 C of chapter VII of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 379g et seq.), in the letters from the Sec-
5 retary of Health and Human Services to the Chairman
6 of the Committee on Health, Education, Labor, and Pen-
7 sions of the Senate and the Chairman of the Committee
8 on Energy and Commerce of the House of Representa-
9 tives, as set forth in the Congressional Record.

10 **SEC. 102. DEFINITIONS.**

11 Section 735 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 379g) is amended—

13 (1) in paragraph (1), in the matter following
14 subparagraph (B), by striking “an allergenic extract
15 product, or” and inserting “does not include an ap-
16 plication with respect to an allergenic extract prod-
17 uct licensed before October 1, 2022, does not include
18 an application with respect to a standardized aller-
19 genic extract product submitted pursuant to a notifi-
20 cation to the applicant from the Secretary regarding
21 the existence of a potency test that measures the al-
22 lergenic activity of an allergenic extract product li-
23 censed by the applicant before October 1, 2022, does
24 not include an application with respect to”;

1 (2) in paragraph (3), in the matter following
2 subparagraph (C)—

3 (A) by inserting “licensed before October
4 1, 2022, a standardized allergenic extract prod-
5 uct submitted pursuant to a notification to the
6 applicant from the Secretary regarding the ex-
7 istence of a potency test that measures the al-
8 lergenic activity of an allergenic extract product
9 licensed by the applicant before October 1,
10 2022,” after “an allergenic extract product”;
11 and

12 (B) by adding at the end the following: “If
13 a written request to place a product in the dis-
14 continued section of either of the lists described
15 in subparagraph (C) is submitted to the Sec-
16 retary on behalf of an applicant, and the re-
17 quest identifies the date the product is, or will
18 be, withdrawn from sale, then, for purposes of
19 assessing the prescription drug program fee
20 under section 736(a)(2), the Secretary shall
21 consider such product to have been included in
22 the discontinued section on the later of (i) the
23 date such request was received, or (ii) if the
24 product will be withdrawn from sale on a future
25 date, such future date when the product is

1 withdrawn from sale. For purposes of subpara-
2 graph (C), a product shall be considered with-
3 drawn from sale once the applicant has ceased
4 its own distribution of the product, whether or
5 not the applicant has ordered recall of all pre-
6 viously distributed lots of the product, except
7 that a routine, temporary interruption in supply
8 shall not render a product withdrawn from
9 sale.”; and

10 (C) by adding at the end the following:

11 “(12) The term ‘skin-test diagnostic product’—

12 “(A) means a product—

13 “(i) for prick, scratch, intradermal, or
14 subcutaneous administration;

15 “(ii) expected to produce a limited,
16 local reaction at the site of administration
17 (if positive), rather than a systemic effect;

18 “(iii) not intended to be a preventive
19 or therapeutic intervention; and

20 “(iv) intended to detect an immediate
21 or delayed-type skin hypersensitivity reac-
22 tion to aid in the diagnosis of—

23 “(I) an allergy to an anti-
24 microbial agent;

1 “(II) an allergy that is not to an
2 antimicrobial agent, if the diagnostic
3 product was authorized for marketing
4 prior to October 1, 2022; or

5 “(III) infection with fungal or
6 mycobacterial pathogens; and

7 “(B) includes positive and negative con-
8 trols required to interpret the results of a prod-
9 uct described in subparagraph (A).”.

10 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

11 (a) TYPES OF FEES.—Section 736(a) of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is
13 amended—

14 (1) in the matter preceding paragraph (1), by
15 striking “2018” and inserting “2023”;

16 (2) in paragraph (1)—

17 (A) in subparagraph (A), by striking “sub-
18 section (c)(5)” each place it appears and insert-
19 ing “subsection (c)(6)”;

20 (B) in subparagraph (C), by inserting
21 “prior to approval” after “or was withdrawn”;
22 and

23 (C) by adding at the end the following:

24 “(H) EXCEPTION FOR SKIN-TEST DIAG-
25 NOSTIC PRODUCTS.—A human drug application

1 for a skin-test diagnostic product shall not be
2 subject to a fee under subparagraph (A).”; and
3 (3) in paragraph (2)—

4 (A) in subparagraph (A)—

5 (i) by striking “subsection (c)(5)” and
6 inserting “subsection (c)(6)”; and

7 (ii) by striking “Except as provided”
8 and inserting the following:

9 “(i) PAYMENT OF FEES.—Except as
10 provided”; and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(ii) PREVIOUSLY DISCONTINUED
14 DRUG PRODUCTS.—If a drug product that
15 is identified in a human drug application
16 approved as of October 1 of a fiscal year
17 is not a prescription drug product as of
18 that date because the drug product is in
19 the discontinued section of a list identified
20 in section 735(3), and on any subsequent
21 day during such fiscal year the drug prod-
22 uct is a prescription drug product, then ex-
23 cept as provided in subparagraphs (B) and
24 (C), each person who is named as the ap-
25 plicant in a human drug application with

1 respect to such product, and who, after
2 September 1, 1992, had pending before the
3 Secretary a human drug application or
4 supplement, shall pay the annual prescrip-
5 tion drug program fee established for a fis-
6 cal year under subsection (c)(6) for such
7 prescription drug product. Such fee shall
8 be due on the last business day of such fis-
9 cal year and shall be paid only once for
10 each product for a fiscal year in which the
11 fee is payable.”; and

12 (B) by amending subparagraph (B) to read
13 as follows:

14 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
15 TION DRUG PRODUCTS.—A prescription drug
16 program fee shall not be assess for a prescrip-
17 tion drug product under subparagraph (A) if
18 such product is—

19 “(i) large volume parenteral product
20 (a sterile aqueous drug product packaged
21 in a single-dose container with a volume
22 greater than or equal to 100 mL, not in-
23 cluding powders for reconstitution or phar-
24 macy bulk packages) identified on the list
25 compiled under section 505(j)(7);

1 “(ii) pharmaceutically equivalent (as
2 defined in section 314.3 of title 21, Code
3 of Federal Regulations (or any successor
4 regulations)), to another product on the
5 list of products compiled under section
6 505(j)(7) (not including the discontinued
7 section of such list); or

8 “(iii) a skin-test diagnostic product.”.

9 (b) FEE REVENUE AMOUNTS.—Section 736(b) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379h(b)) is amended—

12 (1) in paragraph (1)—

13 (A) in the matter preceding subparagraph
14 (A), by striking “2018 through 2022” and in-
15 serting “2023 through 2027”;

16 (B) by redesignating subparagraphs (C)
17 through (F) as subparagraphs (D) through (G),
18 respectively;

19 (C) by inserting after subparagraph (B)
20 the following:

21 “(C) The dollar amount equal to the stra-
22 tegic hiring and retention adjustment for the
23 fiscal year (as determined under subsection
24 (c)(2));”;

1 (D) in subparagraph (D), as so redesignated,
2 nated, by striking “(c)(2)” and inserting
3 “(c)(3)”;

4 (E) in subparagraph (E), as so redesignated,
5 nated, by striking “(c)(3)” and inserting
6 “(c)(4)”;

7 (F) in subparagraph (F), as so redesignated,
8 nated, by striking “(c)(4)” and inserting
9 “(c)(5)”;

10 (G) in subparagraph (G), as so redesignated,
11 nated, by striking clauses (i) through (v) and
12 inserting the following:

13 “(i) \$65,773,693 for fiscal year 2023.

14 “(ii) \$25,097,671 for fiscal year 2024.

15 “(iii) \$14,154,169 for fiscal year
16 2025.

17 “(iv) \$4,864,860 for fiscal year 2026.

18 “(v) \$1,314,620 for fiscal year
19 2027.”; and

20 (2) in paragraph (3)—

21 (A) in subparagraph (A), by striking
22 “2018, \$878,590,000” and inserting “2023,
23 \$1,151,522,958”; and

24 (B) in subparagraph (B)—

- 1 (i) by striking “2019 through 2022”
2 and inserting “2024 through 2027”; and
3 (ii) by striking “subsection (c)(3) or
4 (c)(4)” and inserting “subsection (c)(4) or
5 (c)(5)”.

6 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
7 736(c) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 379h(c)) is amended—

9 (1) in paragraph (1)(B)(ii), by striking “Wash-
10 ington-Baltimore, DC–MD–VA–WV” and inserting
11 “Washington–Arlington–Alexandria, DC–VA–MD–
12 WV”;

13 (2) by redesignating paragraphs (2) through
14 (6) as paragraphs (3) through (7), respectively;

15 (3) by inserting after paragraph (1) the fol-
16 lowing:

17 “(2) STRATEGIC HIRING AND RETENTION AD-
18 JUSTMENT.—For each fiscal year, after the annual
19 base revenue established in subsection (b)(1)(A) is
20 adjusted for inflation in accordance with paragraph
21 (1), the Secretary shall further increase the fee rev-
22 enue and fees—

23 “(A) for fiscal year 2023, by \$9,000,000;
24 and

1 “(B) for fiscal year 2024 and each subse-
2 quent fiscal year, by \$4,000,000.”;

3 (4) in paragraph (3), as so redesignated—

4 (A) in subparagraph (A)—

5 (i) by striking “for inflation”; and

6 (ii) by striking “paragraph (1)” and
7 inserting “paragraphs (1) and (2)”;

8 (B) by amending subparagraph (B) to read
9 as follows:

10 “(B) METHODOLOGY.—For purposes of
11 this paragraph, the Secretary shall employ the
12 capacity planning methodology utilized by the
13 Secretary in setting fees for fiscal year 2021, as
14 described in the notice titled ‘Prescription Drug
15 User Fee Rates for Fiscal Year 2021’ (85 Fed.
16 Reg. 46651; August 3, 2020). The workload
17 categories used in forecasting shall include only
18 the activities described in such notice and, as
19 feasible, additional activities that are directly
20 related to the direct review of applications and
21 supplements, including additional formal meet-
22 ing types, the direct review of postmarketing
23 commitments and requirements, the direct re-
24 view of risk evaluation and mitigation strate-
25 gies, and the direct review of annual reports for

1 approved prescription drug products. Subject to
2 the exceptions in the preceding sentence, the
3 Secretary shall not include as workload cat-
4 egories in forecasting any non-core review ac-
5 tivities, including any activities that the Sec-
6 retary referenced for potential future use in
7 such notice but did not utilize in the setting
8 fees for fiscal year 2021.”;

9 (C) by striking subparagraph (C);

10 (D) by redesignating subparagraphs (D)
11 and (E) as subparagraphs (C) and (D), respec-
12 tively;

13 (E) in subparagraph (C), as so redesign-
14 ated—

15 (i) by striking “year) and” and insert-
16 ing “year),”; and

17 (ii) by inserting “, and subsection
18 (b)(1)(C) (the dollar amount of the stra-
19 tegic hiring and retention adjustment).”;
20 and

21 (F) in subparagraph (D), as so redesign-
22 ated, by striking “paragraph (5)” and insert-
23 ing “paragraph (6)”;

24 (5) in paragraph (4), as so redesignated—

1 (A) by amending subparagraph (A) to read
2 as follows:

3 “(A) INCREASE.—For fiscal year 2023 and
4 subsequent fiscal years, the Secretary shall, in
5 addition to adjustments under paragraphs (1),
6 (2), and (3), further increase the fee revenue
7 and fees if such an adjustment is necessary to
8 provide for at least the following amounts of op-
9 erating reserves of carryover user fees for the
10 process for the review of human drug applica-
11 tions for each fiscal year, as follows:

12 “(i) For fiscal year 2023, at least 8
13 weeks of operating reserves.

14 “(ii) For fiscal year 2024, at least 9
15 weeks of operating reserves.

16 “(iii) For fiscal year 2025 and subse-
17 quent fiscal years, at least 10 weeks of op-
18 erating reserves.”; and

19 (B) in subparagraph (C), by striking
20 “paragraph (5)” and inserting “paragraph
21 (6)”;

22 (6) by amending paragraph (5), as so redesign-
23 nated, to read as follows:

24 “(5) ADDITIONAL DIRECT COST ADJUST-
25 MENT.—The Secretary shall, in addition to adjust-

1 ments under paragraphs (1), (2), (3), and (4), fur-
2 ther increase the fee revenue and fees—

3 “(A) for fiscal year 2023, by \$44,386,150;

4 and

5 “(B) for fiscal years 2024 through 2027,

6 by the amount set forth in clauses (i) through

7 (iv), as applicable, multiplied by the Consumer

8 Price Index for urban consumers (Washington–

9 Arlington–Alexandria, DC–VA–MD–WV; Not

10 Seasonally Adjusted; All Items; Annual Index)

11 for the most recent year of available data, di-

12 vided by such Index for 2021—

13 “(i) for fiscal year 2024, \$60,967,993;

14 “(ii) for fiscal year 2025,

15 \$35,799,314;

16 “(iii) for fiscal year 2026,

17 \$35,799,314; and

18 “(iv) for fiscal year 2027,

19 \$35,799,314.”; and

20 (7) in paragraph (6), as so redesignated, by

21 striking “2017” and inserting “2022”.

22 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-

23 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic

24 Act (21 U.S.C. 379h(g)(3)) is amended by striking “2018

25 through 2022” and inserting “2023 through 2027”.

1 (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-
2 TIONS, AND REFUNDS.—Section 736(i) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is
4 amended to read as follows:

5 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
6 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
7 CERNING FEES.—To qualify for consideration for a waiver
8 or reduction under subsection (d), and exemption under
9 subsection (k), or the return of any fee paid under this
10 section, including if the fee is claimed to have been paid
11 in error, a person shall submit to the Secretary a written
12 request justifying such waiver, reduction, exemption, or
13 return not later than 180 days after such fee is due. A
14 request submitted under this paragraph shall include any
15 legal authorities under which the request is made.”.

16 (f) ORPHAN DRUGS.—Section 736(k) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is
18 amended—

19 (1) in paragraph (1)(B), by striking “during
20 the previous year” and inserting “, as determined
21 under paragraph (2)”; and

22 (2) in paragraph (2), by striking “that its gross
23 annual revenues” and all that follows through the
24 period at the end and inserting “supported by tax
25 returns submitted to the Internal Revenue Service,

1 or, as necessary, by other appropriate financial in-
2 formation, that its gross annual revenues did not ex-
3 ceed \$50,000,000 for the last calendar year ending
4 prior to the fiscal year for which the exemption is
5 requested.”.

6 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.**

7 Section 736B of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 379h–2) is amended—

9 (1) by striking “2018” each place it appears
10 and inserting “2023”; and

11 (2) by striking “Prescription Drug User Fee
12 Amendments of 2017” each place it appears and in-
13 serting “Prescription Drug User Fee Amendments
14 of 2022”;

15 (3) in subsection (a)(4), by striking “2020” and
16 inserting “2023”; and

17 (4) in subsection (f), by striking “2022” each
18 place it appears and inserting “2027”.

19 **SEC. 105. SUNSET DATES.**

20 (a) AUTHORIZATION.—Sections 735 and 736 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
22 379h) shall cease to be effective October 1, 2027.

23 (b) REPORTING REQUIREMENTS.—Section 736B of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379h–2) shall cease to be effective January 31, 2028.

1 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
2 ber 1, 2022, subsections (a) and (b) of section 104 of the
3 FDA Reauthorization Act of 2017 (Public Law 115–52)
4 are repealed.

5 **SEC. 106. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect
7 on October 1, 2022, or the date of the enactment of this
8 Act, whichever is later, except that fees under part 2 of
9 subchapter C of chapter VII of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 379g et seq.) shall be as-
11 sessed for all human drug applications received on or after
12 October 1, 2022, regardless of the date of the enactment
13 of this Act.

14 **SEC. 107. SAVINGS CLAUSE.**

15 Notwithstanding the amendments made by this title,
16 part 2 of subchapter C of chapter VII of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in
18 effect on the day before the date of the enactment of this
19 title, shall continue to be in effect with respect to human
20 drug applications and supplements (as defined in such
21 part as of such day) that were accepted by the Food and
22 Drug Administration for filing on or after October 1,
23 2017, but before October 1, 2022, with respect to assess-
24 ing and collecting any fee required by such part for a fiscal
25 year prior to fiscal year 2023.

1 **TITLE II—FEES RELATING TO**
 2 **DEVICES**

3 **SEC. 201. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
 5 “Medical Device User Fee Amendments of 2022”.

6 (b) **FINDING.**—Congress finds that the fees author-
 7 ized under the amendments made by this title will be dedi-
 8 cated toward expediting the process for the review of de-
 9 vice applications and for assuring the safety and effective-
 10 ness of devices, as set forth in the goals identified for pur-
 11 poses of part 3 of subchapter C of chapter VII of the Fed-
 12 eral Food, Drug, and Cosmetic Act in the letters from the
 13 Secretary of Health and Human Services to the Chairman
 14 of the Committee on Health, Education, Labor, and Pen-
 15 sions of the Senate and the Chairman of the Committee
 16 on Energy and Commerce of the House of Representa-
 17 tives, as set forth in the Congressional Record.

18 **SEC. 202. DEFINITIONS.**

19 Section 737 of the Federal Food, Drug, and Cosmetic
 20 Act (21 U.S.C. 379i) is amended—

21 (1) in paragraph (9)—

22 (A) in the matter preceding subparagraph

23 (A), by striking “and premarket notification
 24 submissions” and inserting “premarket notifica-

1 tion submissions, and de novo classification re-
2 quests”;

3 (B) in subparagraph (D), by striking “and
4 submissions” and inserting “submissions, and
5 de novo classification requests”;

6 (C) in subparagraph (F), by striking “and
7 premarket notification submissions” and insert-
8 ing “premarket notification submissions, and de
9 novo classification requests”;

10 (D) in subparagraphs (G) and (H), by
11 striking “or submissions” each place it appears
12 and inserting “submissions, or requests”; and

13 (E) in subparagraph (K), by striking “or
14 premarket notification submissions” and insert-
15 ing “premarket notification submissions, or de
16 novo classification requests”; and

17 (2) in paragraph (11), by striking “2016” and
18 inserting “2021”.

19 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

20 (a) TYPES OF FEES.—Section 738(a) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is
22 amended—

23 (1) in paragraph (1), by striking “2018” and
24 inserting “2023”; and

25 (2) in paragraph (2)—

1 (A) in subparagraph (A)—

2 (i) in the matter preceding clause (i),
3 by striking “2017” and inserting “2022”;

4 (ii) in clause (iii), by striking “75 per-
5 cent” and inserting “80 percent”; and

6 (iii) in clause (viii), by striking “3.4
7 percent” and inserting “4.5 percent”;

8 (B) in subparagraph (B)(iii), by striking
9 “or premarket notification submission” and in-
10 sserting “premarket notification submission, or
11 de novo classification request”; and

12 (C) in subparagraph (C), by striking “or
13 periodic reporting concerning a class III device”
14 and inserting “periodic reporting concerning a
15 class III device, or de novo classification re-
16 quest”.

17 (b) FEE AMOUNTS.—Section 738(b) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is
19 amended—

20 (1) in paragraph (1), by striking “2018
21 through 2022” and inserting “2023 through 2027”;

22 (2) by amending the table in paragraph (2) to
23 read as follows:

23

“Fee Type	Fiscal Year 2023	Fiscal Year 2024	Fiscal Year 2025	Fiscal Year 2026	Fiscal Year 2027
Premarket Appli- cation	\$425,000	\$435,000	\$445,000	\$455,000	\$470,000
Establishment Registration	\$6,250	\$6,875	\$7,100	\$7,575	\$8,465”;

1 and

2 (3) in paragraph (3), by amending subpara-
3 graphs (A) through (E) to read as follows:

4 “(A) \$312,606,000 for fiscal year 2023.

5 “(B) \$335,750,000 for fiscal year 2024.

6 “(C) \$350,746,400 for fiscal year 2025.

7 “(D) \$366,486,300 for fiscal year 2026.

8 “(E) \$418,343,000 for fiscal year 2027.”.

9 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
10 738(c) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379j(c)) is amended—

12 (1) in paragraph (1), by striking “2017” and
13 inserting “2022”;

14 (2) in paragraph (2)—

15 (A) by striking “2018” each place it ap-
16 pears and inserting “2023”;

17 (B) in subparagraph (B)(ii), by striking
18 “2016” and inserting “2022”;

19 (C) in subparagraph (C)(i)(II), by striking
20 “Washington-Baltimore, DC–MD–VA–WV”

1 and inserting “Washington–Arlington–Alexan-
2 dria, DC–VA–MD–WV”; and

3 (D) in subparagraph (D), by striking
4 “2022” and inserting “2027”;

5 (3) in paragraph (3), by striking “2018
6 through 2022” and inserting “2023 through 2027”;

7 (4) by redesignating paragraphs (4) and (5) as
8 paragraphs (7) and (8), respectively; and

9 (5) by inserting after paragraph (3) the fol-
10 lowing:

11 “(4) PERFORMANCE IMPROVEMENT ADJUST-
12 MENT.—

13 “(A) IN GENERAL.—For each of fiscal
14 years 2025 through 2027, after the adjustment
15 under paragraph (3), the base establishment
16 registration fee amounts for such fiscal year
17 shall be increased to reflect changes in the re-
18 source needs of the Secretary due to improved
19 review performance goals for the process for the
20 review of device applications identified in the
21 letters described in section 201(b) of the Med-
22 ical Device User Fee Amendments of 2022, as
23 the Secretary determines necessary to achieve
24 an increase in total fee collections for such fis-

1 cal year, equal to the following amounts, as ap-
2 plicable:

3 “(i) For fiscal year 2025, the product
4 of—

5 “(I) the amount determined
6 under subparagraph (B)(i)(I); and

7 “(II) the applicable inflation ad-
8 justment under paragraph (2)(B) for
9 such fiscal year.

10 “(ii) For fiscal year 2026, the product
11 of—

12 “(I) the sum of the amounts de-
13 termined under subparagraphs
14 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
15 and

16 “(II) the applicable inflation ad-
17 justment under paragraph (2)(B) for
18 such fiscal year.

19 “(iii) For fiscal year 2027, the prod-
20 uct of—

21 “(I) the sum of the amounts de-
22 termined under subparagraphs
23 (B)(i)(III), (B)(ii)(II), and
24 (B)(iii)(II); and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(B) AMOUNTS.—

5 “(i) PRE-SUBMISSION AMOUNT.—For
6 purposes of subparagraph (A), with respect
7 to the presubmission written feedback goal,
8 the amounts determined under this sub-
9 paragraph are as follows:

10 “(I) For fiscal year 2025,
11 \$15,396,600 if the goal for fiscal year
12 2023 is met.

13 “(II) For fiscal year 2026—

14 “(aa) \$15,396,600 if the
15 goal for fiscal year 2023 is met
16 and the goal for fiscal year 2024
17 is missed; or

18 “(bb) \$36,792,200 if the
19 goal for fiscal year 2024 is met.

20 “(III) For fiscal year 2027—

21 “(aa) \$15,396,600 if the
22 goal for fiscal year 2023 is met
23 and the goal for each of fiscal
24 years 2024 and 2025 is missed;

1 “(bb) \$36,792,200 if the
2 goal for fiscal year 2024 is met
3 and the goal for fiscal year 2025
4 is missed; or

5 “(cc) \$40,572,600 if the
6 goal for fiscal year 2025 is met.

7 “(ii) DE NOVO CLASSIFICATION RE-
8 QUEST AMOUNT.—For purposes of sub-
9 paragraph (A), with respect to the de novo
10 decision goal, the amounts determined
11 under this subparagraph are as follows:

12 “(I) For fiscal year 2026,
13 \$6,323,500 if the goal for fiscal year
14 2023 is met.

15 “(II) For fiscal year 2027—

16 “(aa) \$6,323,500 if the goal
17 for fiscal year 2023 is met and
18 the goal for fiscal year 2024 is
19 missed; or

20 “(bb) \$11,765,400 if the
21 goal for fiscal year 2024 is met.

22 “(iii) PREMARKET NOTIFICATION AND
23 PREMARKET APPROVAL AMOUNT.—For
24 purposes of subparagraph (A), with respect
25 to the 510(k) decision goal, 510(k) shared

1 outcome total time to decision goal, PMA
2 decision goal, and PMA shared outcome
3 total time to decision goal, the amounts de-
4 termined under this subparagraph are as
5 follows:

6 “(I) For fiscal year 2026,
7 \$1,020,000 if the 4 goals for fiscal
8 year 2023 are met.

9 “(II) For fiscal year 2027—

10 “(aa) \$1,020,000 if the 4
11 goals for fiscal year 2023 are met
12 and one or more of the 4 goals
13 for fiscal year 2024 is missed; or

14 “(bb) \$3,906,000 if the 4
15 goals for fiscal year 2024 are
16 met.

17 “(C) PERFORMANCE CALCULATION.—For
18 purposes of this paragraph, performance of the
19 following goals shall be determined as specified
20 in the letters described in section 201(b) of the
21 Medical Device User Fee Amendments of 2022
22 and based on data available as of the applicable
23 dates as follows:

24 “(i) The performance of the pre-sub-
25 mission written feedback goal—

1 “(I) for fiscal year 2023, shall be
2 based on data available as of March
3 31, 2024;

4 “(II) for fiscal year 2024, shall
5 be based on data available as of
6 March 31, 2025; and

7 “(III) for fiscal year 2025, shall
8 be based on data available as of
9 March 31, 2026.

10 “(ii) The performance of the de novo
11 decision goal, 510(k) decision goal, 510(k)
12 shared outcome total time to decision goal,
13 PMA decision goal, and PMA shared out-
14 come total time to decision goal—

15 “(I) for fiscal year 2023, shall be
16 based on data available as of March
17 31, 2025; and

18 “(II) for fiscal year 2024, shall
19 be based on data available as of
20 March 31, 2026.

21 “(D) DEFINITIONS.—For purposes of this
22 paragraph, the terms ‘pre-submission written
23 feedback goal’, ‘de novo decision goal’, ‘510(k)
24 decision goal’, ‘510(k) shared outcome total
25 time to decision goal’, ‘PMA decision goal’, and

1 ‘PMA shared outcome total time to decision
2 goal’ have the meanings given such terms in the
3 goals identified in the letters described in sec-
4 tion 201(b) of the Medical Device User Fee
5 Amendments of 2022.

6 “(5) HIRING ADJUSTMENT.—

7 “(A) IN GENERAL.—For each of fiscal
8 years 2025 through 2027, after the adjust-
9 ments under paragraphs (3) and (4), if applica-
10 ble, the base establishment registration fee
11 amounts shall be decreased as the Secretary de-
12 termines necessary to achieve a reduction in
13 total fee collections equal to the hiring adjust-
14 ment amount under subparagraph (B), if the
15 number of hires to support the process for the
16 review of device applications falls below the fol-
17 lowing thresholds for the applicable fiscal years:

18 “(i) For fiscal year 2025, 85 percent
19 of the hiring goal specified in subpara-
20 graph (C) for fiscal year 2023.

21 “(ii) For fiscal year 2026, 90 percent
22 of the hiring goal specified in subpara-
23 graph (C) for fiscal year 2024.

1 “(iii) For fiscal year 2027, 90 percent
2 of the hiring goal specified in subpara-
3 graph (C) for fiscal year 2025.

4 “(B) HIRING ADJUSTMENT AMOUNT.—The
5 hiring adjustment amount for fiscal year 2025
6 and each subsequent fiscal year is the product
7 of—

8 “(i) the number of hires by which the
9 hiring goal specified in subparagraph (C)
10 for the fiscal year before the prior fiscal
11 year was missed;

12 “(ii) \$72,877; and

13 “(iii) the applicable inflation adjust-
14 ment under paragraph (2)(B) for the fiscal
15 year for which the hiring goal was missed.

16 “(C) HIRING GOALS.—

17 “(i) IN GENERAL.—For purposes of
18 subparagraph (B), the hiring goals for
19 each of fiscal years 2023 through 2025 are
20 as follows:

21 “(I) For fiscal year 2023, 144
22 hires.

23 “(II) For fiscal year 2024, 42
24 hires.

25 “(III) For fiscal year 2025—

1 “(aa) 24 hires if the base es-
2 tablishment registration fees are
3 not increased by the amount de-
4 termined under paragraph
5 (4)(A)(i); or

6 “(bb) 83 hires if the base
7 establishment registration fees
8 are increased by the amount de-
9 termined under paragraph
10 (4)(A)(i).

11 “(ii) NUMBER OF HIRES.—For pur-
12 poses of this paragraph, the number of
13 hires **【for a fiscal year】** shall be deter-
14 mined by the Secretary, as set forth in the
15 letters described in **【section 201(b) of the**
16 **Medical Device User Fee Amendments of**
17 **2022】**.

18 “(6) OPERATING RESERVE ADJUSTMENT.—

19 “(A) IN GENERAL.—For each of fiscal
20 years 2023 through 2027, after the adjust-
21 ments under paragraphs (3), (4), and (5), if ap-
22 plicable, if the Secretary has operating reserves
23 of carryover user fees for the process for the re-
24 view of device applications in excess of the des-
25 ignated amount in subparagraph (B), the Sec-

1 retary shall decrease the base establishment
2 registration fee amounts to provide for not
3 more than such designated amount of operating
4 reserves.

5 “(B) DESIGNATED AMOUNT.—Subject to
6 subparagraph (C), for each fiscal year, the des-
7 ignated amount in this subparagraph is equal
8 to the sum of—

9 “(i) 13 weeks of operating reserves of
10 carryover user fees; and

11 “(ii) the 1 month of operating re-
12 serves described in paragraph (8).

13 “(C) EXCLUDED AMOUNT.—For the period
14 of fiscal years 2023 through 2026, a total
15 amount equal to \$118,000,000 shall not be con-
16 sidered part of the designated amount under
17 subparagraph (B) and shall not be subject to
18 the decrease under subparagraph (A).”.

19 (d) SMALL BUSINESSES.—Section 738 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
21 ed—

22 (1) in subsection (d)(2)(B)(iii), by inserting “,
23 if extant,” after “national taxing authority”; and

24 (2) in subsection (e)(2)(B)(iii), by inserting “,
25 if extant,” after “national taxing authority”.

1 (e) CONDITIONS.—Section 738(g) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is
3 amended—

4 (1) in paragraph (1)(A), by striking
5 “\$320,825,000” and inserting “\$398,566,000”; and

6 (2) in paragraph (2), by inserting “de novo
7 classification requests,” after “class III device,”.

8 (f) AUTHORIZATION OF APPROPRIATIONS.—Section
9 738(h)(3) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 379j(h)(3)) is amended to read as follows:

11 “(3) AUTHORIZATION OF APPROPRIATIONS.—

12 “(A) IN GENERAL.—For each of the fiscal
13 years 2023 through 2027, there is authorized to
14 be appropriated for fees under this section an
15 amount equal to the revenue amount deter-
16 mined in subparagraph (B), less the amount of
17 reductions determined in subparagraph (C).

18 “(B) REVENUE AMOUNT.—For purposes of
19 this paragraph, the revenue amount for each
20 fiscal year is the sum of—

21 “(i) the total revenue amount under
22 subsection (b)(3) for the fiscal year, as ad-
23 justed under paragraphs (1), (2), and (3)
24 of subsection (c); and

1 “(ii) the performance improvement
2 adjustment amount for the fiscal year
3 under subsection (c)(4)(A), if applicable.

4 “(C) AMOUNT OF REDUCTIONS.—For pur-
5 poses of this paragraph, the amount of reduc-
6 tions for each fiscal year is the sum of—

7 “(i) the hiring adjustment amount for
8 the fiscal year under subsection (c)(5), if
9 applicable; and

10 “(ii) the operating reserve adjustment
11 amount for the fiscal year under sub-
12 section (c)(6), if applicable.”.

13 **SEC. 204. ACCREDITATION PROGRAMS.**

14 (a) ACCREDITATION SCHEME FOR CONFORMITY AS-
15 SESSMENT.—Section 514(d) of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 360d(d)) is amended—

17 (1) in the subsection heading, by striking
18 “PILOT”;

19 (2) in paragraph (1)—

20 (A) in the matter preceding subparagraph
21 (A), by striking “pilot”;

22 (B) in subparagraph (A)—

23 (i) by inserting “meeting criteria spec-
24 ified by the Secretary in guidance” after
25 “testing laboratories”;

1 (ii) by inserting “in guidance” after
2 “by the Secretary”; and

3 (iii) by striking “assess the conform-
4 ance of a device with” and inserting “con-
5 duct testing to support the assessment of
6 the conformance of a device to”; and

7 (C) in subparagraph (B)—

8 (i) by striking “determinations” and
9 inserting “results”;

10 (ii) by inserting “to support” after
11 “so accredited”; and

12 (iii) by striking “a particular such de-
13 termination” and inserting “particular
14 such results”;

15 (3) in paragraph (2)—

16 (A) in the paragraph heading, by striking
17 “DETERMINATIONS” and inserting “RESULTS”;

18 (B) in subparagraph (A)—

19 (i) by striking “determinations by
20 testing laboratories” and all that follows
21 through “such determinations or” and in-
22 sserting “results by testing laboratories ac-
23 credited pursuant to this subsection, in-
24 cluding by conducting periodic audits of
25 such results or of the”;

1 (ii) by inserting a comma after “or
2 testing laboratories”;

3 (iii) by inserting “or recognition of an
4 accreditation body” after “accreditation of
5 such testing laboratory”; and

6 (iv) by striking “such device” and in-
7 serting “a device”; and

8 (C) in subparagraph (B), by striking “by
9 a testing laboratory so accredited” and insert-
10 ing “under this subsection”; and

11 (D) by inserting “or recognition of an ac-
12 creditation body” before “under paragraph
13 (1)(A)”;

14 (4) in paragraph (3)(C)—

15 (A) in the subparagraph heading, by in-
16 serting “AND TRANSITION” after “INITIATION”;
17 and

18 (B) by adding at the end the following:
19 “After September 30, 2023, such pilot program
20 will be considered to be completed, and the Sec-
21 retary shall have the authority to continue oper-
22 ating a program consistent with this sub-
23 section.”; and

24 (5) by striking paragraph (4).

1 (b) ACCREDITED PERSONS.—Section 523(c) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 360m(c)) is amended by striking “2022” and inserting
4 “2027”.

5 **SEC. 205. SUNSET DATES.**

6 (a) AUTHORIZATION.—Sections 737 and 738 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
8 379fj) shall cease to be effective October 1, 2027.

9 (b) REPORTING REQUIREMENTS.—Section 738A of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379j–1) shall cease to be effective January 31, 2028.

12 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
13 ber 1, 2022, subsections (a) and (b) of section 210 of the
14 FDA Reauthorization Act of 2017 (Public Law 115–52)
15 are repealed.

16 **SEC. 206. EFFECTIVE DATE.**

17 The amendments made by this title shall take effect
18 on October 1, 2022, or the date of the enactment of this
19 Act, whichever is later, except that fees under part 3 of
20 subchapter C of chapter VII of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 379i et seq.) shall be as-
22 sessed for all human drug applications received on or after
23 October 1, 2022, regardless of the date of the enactment
24 of this Act.

1 **SEC. 207. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 3 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to the sub-
7 missions listed in section 738(a)(2)(A) of such Act (as de-
8 fined in such part as of such day) that on or after October
9 1, 2017, but before October 1, 2022, were accepted by
10 the Food and Drug Administration for filing with respect
11 to assessing and collecting any fee required by such part
12 for a fiscal year prior to fiscal year 2023.

13 **TITLE III—FEES RELATING TO**
14 **GENERIC DRUGS**

15 **SEC. 301. SHORT TITLE; FINDING.**

16 (a) **SHORT TITLE.**—This title may be cited as the
17 “Generic Drug User Fee Amendments of 2022”.

18 (b) **FINDING.**—The Congress finds that the fees au-
19 thorized by the amendments made in this title will be dedi-
20 cated to human generic drug activities, as set forth in the
21 goals identified for purposes of part 7 of subchapter C
22 of chapter VII of the Federal Food, Drug, and Cosmetic
23 Act, in the letters from the Secretary of Health and
24 Human Services to the Chairman of the Committee on
25 Health, Education, Labor, and Pensions of the Senate and
26 the Chairman of the Committee on Energy and Commerce

1 of the House of Representatives, as set forth in the Con-
2 gressional Record.

3 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG FEES.**

5 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
7 42(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
9 striking “2018” and inserting “2023”;

10 (2) in paragraph (2)(C), by striking “fiscal
11 years 2018 through 2022” and inserting “fiscal
12 years 2023 through 2027”;

13 (3) in paragraph (3)(B), by striking “fiscal
14 years 2018 through 2022” and inserting “fiscal
15 years 2023 through 2027”;

16 (4) in paragraph (4)(D), by striking “fiscal
17 years 2018 through 2022” and inserting “fiscal
18 years 2023 through 2027”; and

19 (5) in paragraph (5)(D), by striking “fiscal
20 years 2018 through 2022” and inserting “fiscal
21 years 2023 through 2027”.

22 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379j-42(b)) is amended—

25 (1) in paragraph (1)—

1 (A) in subparagraph (A)—

2 (i) in the heading, by striking “2018”
3 and inserting “2023”;

4 (ii) by striking “2018” and inserting
5 “2023”; and

6 (iii) by striking “\$493,600,000” and
7 inserting [“\$582,500,000”]; and

8 (B) in subparagraph (B)—

9 (i) in the heading, by striking “2019
10 THROUGH 2022” and inserting “2024
11 THROUGH 2027”;

12 (ii) by striking “For each” and insert-
13 ing the following:

14 “(i) IN GENERAL.—For each”;

15 (iii) by striking “2019 through 2022”
16 and inserting “2024 through 2027”;

17 (iv) by striking “\$493,600,000” and
18 inserting “the base revenue amount under
19 clause (ii)”;

20 (v) by adding at the end the following:

21 “(ii) BASE REVENUE AMOUNT.—The
22 base revenue amount for a fiscal year is
23 the total revenue amount established under
24 this paragraph for the previous fiscal year,
25 not including any adjustments made for

1 such previous fiscal year under subsection
2 (c)(3).”; and

3 (2) in paragraph (2)—

4 (A) in subparagraph (C), by striking “one-
5 third the amount” and inserting “24 percent”;

6 (B) in subparagraph (D), by striking
7 “Seven” and inserting “Six”; and

8 (C) in subparagraph (E)(i), by striking
9 “Thirty-five” and inserting “Thirty-six”.

10 (c) ADJUSTMENTS.—Section 744B(c) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is
12 amended—

13 (1) in paragraph (1)—

14 (A) in the matter preceding subparagraph

15 (A)—

16 (i) by striking “2019” and inserting
17 “2024”; and

18 (ii) by striking “the product of the
19 total revenues established in such notice
20 for the prior fiscal year” and inserting
21 “the base revenue amount for the fiscal
22 year determined under subsection
23 (b)(1)(B)(ii)”; and

24 (B) in subparagraph (C), by striking
25 “Washington-Baltimore, DC–MD–VA–WV”

1 and inserting “Washington-Arlington-Alexan-
2 dria, DC–VA–MD–WV”; and

3 (2) by striking paragraph (2) and inserting the
4 following:

5 “(2) CAPACITY PLANNING ADJUSTMENT.—

6 “(A) IN GENERAL.—Beginning with fiscal
7 year 2024, the Secretary shall, in addition to
8 the adjustment under paragraph (1), further in-
9 crease the fee revenue and fees under this sec-
10 tion for a fiscal year, in accordance with this
11 paragraph, to reflect changes in the resource
12 capacity needs of the Secretary for human ge-
13 neric drug activities.

14 “(B) CAPACITY PLANNING METHOD-
15 OLOGY.—The Secretary shall establish a capac-
16 ity planning methodology for purposes of this
17 paragraph, which shall—

18 “(i) be derived from the methodology
19 and recommendations made in the report
20 titled ‘Independent Evaluation of the
21 GDUFA Resource Capacity Planning Ad-
22 justment Methodology: Evaluation and
23 Recommendations’ as announced in the
24 Federal Register on August 3, 2020 (85
25 Fed. Reg. 46658); and

1 “(ii) incorporate approaches and at-
2 tributes determined appropriate by the
3 Secretary, including those made in such re-
4 port recommendations, except the workload
5 categories used in forecasting resources
6 shall only be those specified in section
7 VIII.B.2.e. of the letters described in sec-
8 tion 301(b) of the Generic Drug User Fee
9 Amendments of 2022.

10 “(C) LIMITATIONS.—

11 “(i) IN GENERAL.—Under no cir-
12 cumstances shall an adjustment under this
13 paragraph result in fee revenue for a fiscal
14 year that is less than the sum of the
15 amounts under subsection (b)(1)(B)(ii)
16 (the base revenue amount for the fiscal
17 year) and paragraph (1) (the dollar
18 amount of the inflation adjustment for the
19 fiscal year).

20 “(ii) ADDITIONAL LIMITATION.—An
21 adjustment under this paragraph shall not
22 exceed 3 percent of the sum described in
23 clause (i) for the fiscal year, except that
24 such limitation shall be 4 percent if—

1 “(I) for purposes of an adjust-
2 ment for fiscal year 2024, the Sec-
3 retary determines that, during the pe-
4 riod from April 1, 2021, through
5 March 31, 2023—

6 “(aa) the total number of
7 abbreviated new drug applica-
8 tions submitted was greater than
9 or equal to 2,000; or

10 “(bb) thirty-five percent or
11 more of abbreviated new drug ap-
12 plications submitted related to
13 complex products (as that term is
14 defined in section XI of the let-
15 ters described in section 301(b)
16 of the Generic Drug User Fee
17 Amendments of 2022);

18 “(II) for purposes of an adjust-
19 ment for fiscal year 2025, the Sec-
20 retary determines that, during the pe-
21 riod from April 1, 2022, through
22 March 31, 2024—

23 “(aa) the total number of
24 abbreviated new drug applica-

1 tions submitted was greater than
2 or equal to 2,300; or

3 “(bb) thirty-five percent or
4 more of abbreviated new drug ap-
5 plications submitted related to
6 complex products (as so defined);

7 “(III) for purposes of an adjust-
8 ment for fiscal year 2026, the Sec-
9 retary determines that, during the pe-
10 riod from April 1, 2023, through
11 March 31, 2025—

12 “(aa) the total number of
13 abbreviated new drug applica-
14 tions submitted was greater than
15 or equal to 2,300; or

16 “(bb) thirty-five percent or
17 more of abbreviated new drug ap-
18 plications submitted related to
19 complex products (as so defined);
20 and

21 “(IV) for purposes of an adjust-
22 ment for fiscal year 2027, the Sec-
23 retary determines that, during the pe-
24 riod from April 1, 2024, through
25 March 31, 2026—

1 “(aa) the total number of
2 abbreviated new drug applica-
3 tions submitted was greater than
4 or equal to 2,300; or

5 “(bb) thirty-five percent or
6 more of abbreviated new drug ap-
7 plications submitted related to
8 complex products (as so defined).

9 “(D) PUBLICATION IN FEDERAL REG-
10 ISTER.—The Secretary shall publish in the Fed-
11 eral Register notice under subsection (a), the
12 fee revenue and fees resulting from the adjust-
13 ment and the methodology under this para-
14 graph.

15 “(3) OPERATING RESERVE ADJUSTMENT.—

16 “(A) IN GENERAL.—For fiscal year 2024
17 and subsequent fiscal years, the Secretary may,
18 in addition to adjustments under paragraphs
19 (1) and (2), further increase the fee revenue
20 and fees under this section if such an adjust-
21 ment is necessary to provide operating reserves
22 of carryover user fees for human generic drug
23 activities for not more than the number of
24 weeks specified in subparagraph (B).

1 “(B) NUMBER OF WEEKS.—The number of
2 weeks specified in this subparagraph is—

3 “(i) 8 weeks for fiscal year 2024;

4 “(ii) 9 weeks for fiscal year 2025; and

5 “(iii) 10 weeks for each of fiscal year
6 2026 and 2027.

7 “(C) DECREASE.—If the Secretary has
8 carryover balances for human generic drug ac-
9 tivities in excess of 12 weeks of the operating
10 reserves referred to in subparagraph (A), the
11 Secretary shall decrease the fee revenue and
12 fees referred to in such subparagraph to provide
13 for not more than 12 weeks of such operating
14 reserves.

15 “(D) RATIONALE FOR ADJUSTMENT.—If
16 an adjustment under this paragraph is made,
17 the rationale for the amount of the increase or
18 decrease (as applicable) in fee revenue and fees
19 shall be contained in the annual Federal Reg-
20 ister notice under subsection (a) publishing the
21 fee revenue and fees for the fiscal year in-
22 volved.”.

23 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j-42(d)(1)) is amended—

1 (1) in the heading, by striking “2018 THROUGH
2 2022” and inserting “2023 THROUGH 2027”;

3 (2) by striking “more” and inserting “later”;
4 and

5 (3) by striking “2018 through 2022” and in-
6 serting “2023 through 2027”.

7 (e) EFFECT OF FAILURE TO PAY FEES.—The head-
8 ing of paragraph (3) of section 744B(g) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is
10 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
11 FEE”.

12 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
13 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking
15 “2018 through 2022” and inserting “2023 through
16 2027”.

17 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

18 Section 744C of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 379j–43) is amended—

20 (1) in subsection (a)—

21 (A) by striking “2018” each place it ap-
22 pears and inserting “2023”; and

23 (B) by striking “Generic Drug User Fee
24 Amendments of 2017” each place it appears

1 and inserting “Generic Drug User Fee Amend-
2 ments of 2022”;

3 (2) in subsection (b), by striking “2018” and
4 inserting “2023”;

5 (3) in subsection (c)—

6 (A) by striking “2018” and inserting
7 “2023”; and

8 (B) by striking “Generic Drug User Fee
9 Amendments of 2017” each place it appears
10 and inserting “Generic Drug User Fee Amend-
11 ments of 2022”; and

12 (4) in subsection (f)—

13 (A) in paragraph (1), by striking “2022”
14 and inserting “2027”; and

15 (B) in paragraph (5), by striking “January
16 15, 2022” and inserting “January 15, 2027”.

17 **SEC. 304. SUNSET DATES.**

18 (a) **AUTHORIZATION.**—Sections 744A and 744B of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–41; 379j–42) shall cease to be effective October 1,
21 2027.

22 (b) **REPORTING REQUIREMENTS.**—Section 744C of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379j–43) shall cease to be effective January 31, 2028.

1 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
2 ber 1, 2022, subsections (a) and (b) of section 305 of the
3 FDA Reauthorization Act of 2017 (Public Law 115–52)
4 are repealed.

5 **SEC. 305. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect
7 on October 1, 2022, or the date of the enactment of this
8 Act, whichever is later, except that fees under part 7 of
9 subchapter C of chapter VII of the Federal Food, Drug,
10 and Cosmetic Act shall be assessed for all abbreviated new
11 drug applications received on or after October 1, 2022,
12 regardless of the date of the enactment of this Act.

13 **SEC. 306. SAVINGS CLAUSE.**

14 Notwithstanding the amendments made by this title,
15 part 7 of subchapter C of chapter VII of the Federal Food,
16 Drug, and Cosmetic Act, as in effect on the day before
17 the date of the enactment of this title, shall continue to
18 be in effect with respect to abbreviated new drug applica-
19 tions (as defined in such part as of such day) that were
20 received by the Food and Drug Administration within the
21 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
22 355(j)(5)(A)), prior approval supplements that were sub-
23 mitted, and drug master files for Type II active pharma-
24 ceutical ingredients that were first referenced on or after
25 October 1, 2017, but before October 1, 2022, with respect

1 to assessing and collecting any fee required by such part
2 for a fiscal year prior to fiscal year 2023.

3 **TITLE IV—FEES RELATING TO**
4 **BIOSIMILAR BIOLOGICAL**
5 **PRODUCTS**

6 **SEC. 401. SHORT TITLE; FINDING.**

7 (a) **SHORT TITLE.**—This title may be cited as the
8 “Biosimilar User Fee Amendments of 2022”.

9 (b) **FINDING.**—Congress finds that the fees author-
10 ized by the amendments made in this title will be dedi-
11 cated to expediting the process for the review of biosimilar
12 biological product applications, including postmarket safe-
13 ty activities, as set forth in the goals identified for pur-
14 poses of part 8 of subchapter C of chapter VII of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51
16 et seq.), in the letters from the Secretary of Health and
17 Human Services to the Chairman of the Committee on
18 Health, Education, Labor, and Pensions of the Senate and
19 the Chairman of the Committee on Energy and Commerce
20 of the House of Representatives, as set forth in the Con-
21 gressional Record.

22 **SEC. 402. DEFINITIONS.**

23 Section 744G of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 379j–51) is amended—

25 (1) in paragraph (1)—

1 (A) by striking “Washington-Baltimore,
2 DC–MD–VA–WV” and inserting “Washington–
3 Arlington–Alexandria, DC–VA–MD–WV”;

4 (B) by striking “October of” and inserting
5 “September of”; and

6 (C) by striking “October 2011” and insert-
7 ing “September 2011”; and

8 (2) in paragraph (4)(B)(iii)—

9 (A) by striking subclause (II); and

10 (B) by redesignating subclauses (III) and

11 (IV) as subclauses (II) and (III), respectively.

12 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIO-**
13 **LOGICAL PRODUCT FEES.**

14 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
16 52(a)) is amended—

17 (1) in the matter preceding paragraph (1), by
18 striking “2018” and inserting “2023”;

19 (2) in paragraph (1)—

20 (A) in subparagraph (A)—

21 (i) in clause (iv)(I), by striking “5
22 days” and inserting “7 days”; and

23 (ii) in clause (v)(II), by striking “5
24 days” and inserting “7 days”;

25 (B) in subparagraph (B)—

1 (i) in clause (i), by inserting “except
2 that, in the case that such product (includ-
3 ing, where applicable, ownership of the rel-
4 evant investigational new drug application)
5 is transferred to a licensee, assignee, or
6 successor of such person, and written no-
7 tice of such transfer is provided to the Sec-
8 retary, such licensee, assignee or successor
9 shall pay the annual biosimilar biological
10 product development fee” before the pe-
11 riod;

12 (ii) in clause (iii)—

13 (I) in subclause (I), by striking
14 “; or” and inserting a semicolon;

15 (II) in subclause (II), by striking
16 the period and inserting “; or”; and

17 (III) by adding at the end the
18 following:

19 “(III) been administratively re-
20 moved from the biosimilar biological
21 product development program for the
22 product under subparagraph (E)(v).”;
23 and

24 (iii) in clause (iv), by striking “accept-
25 ed for filing on or after October 1 of such

1 fiscal year” and inserting “subsequently
2 accepted for filing”;

3 (C) in subparagraph (D)—

4 (i) in clause (i)—

5 (I) in the matter preceding sub-
6 clause (I), by striking “shall, if the
7 person seeks to resume participation
8 in such program, pay” and inserting
9 “or who has been administratively re-
10 moved from such program for a prod-
11 uct under subparagraph (E)(v) shall,
12 if the person seeks to resume partici-
13 pation in such program, pay all an-
14 nual biosimilar biological product de-
15 velopment fees previously assessed for
16 such product and still owed and”; and

17 (II) in subclause (I)—

18 (aa) by striking “5 days”
19 and inserting “7 days”; and

20 (bb) by inserting “or the
21 date of administrative removal,
22 as applicable” after “discon-
23 tinued”;

24 (III) in subclause (II), by insert-
25 ing “or the date of administrative re-

1 moval, as applicable” after “discon-
2 tinued”; and

3 (ii) in clause (ii), by inserting “except
4 that, in the case that such product (includ-
5 ing, where applicable, ownership of the rel-
6 evant investigational new drug application)
7 is transferred to a licensee, assignee, or
8 successor of such person, and written no-
9 tice of such transfer is provided to the Sec-
10 retary, such licensee, assignee or successor
11 shall pay the annual biosimilar biological
12 product development fee” before the period
13 at the end; and

14 (D) in subparagraph (E), by adding at the
15 end the following:

16 “(v) ADMINISTRATIVE REMOVAL FROM
17 THE BIOSIMILAR BIOLOGICAL PRODUCT
18 DEVELOPMENT PROGRAM.—If a person has
19 failed to pay an annual biosimilar biologi-
20 cal product development fee for a product
21 as required under subparagraph (B) for a
22 period of 2 consecutive fiscal years, the
23 Secretary may administratively remove
24 such person from the biosimilar biological
25 product development program for the prod-

1 uct. At least 30 days prior to administra-
2 tively removing a person from the bio-
3 similar biological product development pro-
4 gram for a product under this clause, the
5 Secretary shall provide written notice to
6 such person of the intended administrative
7 removal.”;

8 (3) in paragraph (2)(D), by inserting “prior to
9 approval” after “withdrawn”;

10 (4) in paragraph (3)—

11 (A) in subparagraph (A)—

12 (i) in clause (i), by striking “; and”
13 and inserting a semicolon;

14 (ii) by redesignating clause (ii) as
15 clause (iii); and

16 (iii) by inserting the following after
17 clause (i):

18 “(ii) may be dispensed only under pre-
19 scription pursuant to section 503(b); and”;
20 and

21 (B) by adding at the end the following:

22 “(E) MOVEMENT TO DISCONTINUED
23 LIST.—

24 “(i) WRITTEN REQUEST TO PLACE ON
25 DISCONTINUED LIST.—

1 “(I) IN GENERAL.—If a written
2 request to place a product on the list
3 of discontinued biosimilar biological
4 products referred to in subparagraph
5 (A)(iii) is submitted to the Secretary
6 on behalf of an applicant, and the re-
7 quest identifies the date the product
8 is, or will be, withdrawn from sale,
9 then for purposes of assessing the bio-
10 similar biological product program fee,
11 the Secretary shall consider such
12 product to have been included on such
13 list on the later of—

14 “(aa) the date such request
15 was received; or

16 “(bb) if the product will be
17 withdrawn from sale on a future
18 date, such future date when the
19 product is withdrawn from sale.

20 “(II) WITHDRAWN FROM SALE
21 DEFINED.—For purposes of this
22 clause, a product shall be considered
23 withdrawn from sale once the appli-
24 cant has ceased its own distribution of
25 the product, whether or not the appli-

1 cant has ordered recall of all pre-
2 viously distributed lots of the product,
3 except that a routine, temporary
4 interruption in supply shall not render
5 a product withdrawn from sale.

6 “(ii) PRODUCTS REMOVED FROM DIS-
7 CONTINUED LIST.—If a biosimilar biologi-
8 cal product that is identified in a bio-
9 similar biological product application ap-
10 proved as of October 1 of a fiscal year ap-
11 pears, as of October 1 of such fiscal year,
12 on the list of discontinued biosimilar bio-
13 logical products referred to in subpara-
14 graph (A)(iii), and on any subsequent day
15 during such fiscal year the biosimilar bio-
16 logical product does not appear on such
17 list, except as provided in subparagraph
18 (D), each person who is named as the ap-
19 plicant in **【the】** biosimilar biological prod-
20 uct application shall pay the annual bio-
21 similar biological product program fee es-
22 tablished for a fiscal year under subsection
23 (c)(5) for such biosimilar biological prod-
24 uct. Notwithstanding subparagraph (B),
25 such fee shall be due on the last business

1 day of such fiscal year and shall be paid
2 only once for each product for each fiscal
3 year.”; and

4 (5) by striking paragraph (4).

5 (b) FEE REVENUE AMOUNTS.—Section 744H(b) of
6 the Federal Food, Drug, and Cosmetic Act ((21 U.S.C.
7 379j–52(b)) is amended—

8 (1) by striking paragraph (1);

9 (2) by redesignating paragraphs (2) through
10 (4) as paragraphs (1) through (3), respectively;

11 (3) in paragraph (1), as so redesignated—

12 (A) in the paragraph heading, by striking
13 “SUBSEQUENT FISCAL YEARS” and inserting
14 “IN GENERAL”;

15 (B) in the matter preceding subparagraph
16 (A), by striking “2019 through 2022” and in-
17 serting “2023 through 2027”;

18 (C) in subparagraph (A), by striking
19 “paragraph (4)” and inserting “paragraph
20 (3)”;

21 (D) by redesignating subparagraphs (C)
22 and (D) as subparagraphs (D) and (E), respec-
23 tively;

24 (E) by inserting after subparagraph (B)
25 the following:

1 “(C) the dollar amount equal to the stra-
2 tegic hiring and retention adjustment (as deter-
3 mined under subsection (c)(2));”;

4 (F) in subparagraph (D), as so redesign-
5 ated, by striking “subsection (c)(2); and” and
6 inserting “subsection (c)(3));”;

7 (G) in subparagraph (E), as so redesign-
8 ated, by striking “subsection (c)(3).” and in-
9 serting “subsection (c)(4)); and”;

10 (H) by adding at the end the following:

11 “(F) for fiscal years 2023 and 2024, addi-
12 tional dollar amounts equal to—

13 “(i) \$4,428, 886 for fiscal year 2023;

14 and

15 “(ii) \$320,569 for fiscal year 2024.”;

16 (4) in paragraph (2), as so redesignated—

17 (A) in the paragraph heading, by striking
18 “; LIMITATIONS ON FEE AMOUNTS”;

19 (B) by striking subparagraph (B); and

20 (C) by redesignating subparagraphs (C)
21 and (D) as subparagraphs (B) and (C), respec-
22 tively; and

23 (5) by amending paragraph (3), as so redesign-
24 ated, to read as follows:

1 “(3) ANNUAL BASE REVENUE.—For purposes
2 of paragraph (1), the dollar amount of the annual
3 base revenue for a fiscal year shall be—

4 “(A) for fiscal year 2023, \$43,376,922;
5 and

6 “(B) for fiscal years 2024 through 2027,
7 the dollar amount of the total revenue amount
8 established under paragraph (1) for the pre-
9 vious fiscal year, excluding any adjustments to
10 such revenue amount under subsection (c)(4).”.

11 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
12 744H(c) of the Federal Food, Drug, and Cosmetic Act
13 ((21 U.S.C. 379j–52(c)) is amended—

14 (1) in paragraph (1)—

15 (A) in subparagraph (A)—

16 (i) in the matter preceding clause (i),
17 by striking “subsection (b)(2)(B)” and in-
18 serting “subsection (b)(1)(B)”; and

19 (ii) in clause (i), by striking “sub-
20 section (b)” and inserting “subsection
21 (b)(1)(A)”; and

22 (B) in subparagraph (B)(ii), by striking
23 “Washington-Baltimore, DC–MD–VA–WV”
24 and inserting “Washington–Arlington–Alexan-
25 dria, DC–VA–MD–WV”;

1 (2) by striking paragraph (4);

2 (3) by redesignating paragraphs (2) and (3) as
3 paragraphs (3) and (4), respectively;

4 (4) by inserting after paragraph (1) the fol-
5 lowing:

6 “(2) STRATEGIC HIRING AND RETENTION AD-
7 JUSTMENT.—For each fiscal year beginning in fiscal
8 year 2023, after the annual base revenue under sub-
9 section (b)(1)(A) is adjusted for inflation in accord-
10 ance with paragraph (1), the Secretary shall further
11 increase the fee revenue and fees by \$150,000.”;

12 (5) in paragraph (3), as so redesignated—

13 (A) in subparagraph (A)—

14 (i) by striking “Beginning with the
15 fiscal year described in subparagraph
16 (B)(ii)(II)” and inserting “For each fiscal
17 year”; and

18 (ii) by striking “adjustment under
19 paragraph (1), further increase” and in-
20 sserting “adjustments under paragraphs (1)
21 and (2), further adjust”; and

22 (B) by amending subparagraph (B) to read
23 as follows:

24 “(B) METHODOLOGY.—For purposes of
25 this paragraph, the Secretary shall employ the

1 capacity planning methodology utilized by the
2 Secretary in setting fees for fiscal year 2021, as
3 described in the notice as described in the no-
4 tice titled ‘Biosimilar User Fee Rates for Fiscal
5 Year 2021’ (85 Fed. Reg. 47220; August 4,
6 2020). The workload categories used in fore-
7 casting shall include only the activities de-
8 scribed in such notice and, as feasible, addi-
9 tional activities that are also directly related to
10 the direct review of biosimilar biological product
11 applications and supplements, including addi-
12 tional formal meeting types and the direct re-
13 view of postmarketing commitments and re-
14 quirements, the direct review of risk evaluation
15 and mitigation strategies, and the direct review
16 of annual reports for approved biosimilar bio-
17 logical products. Subject to the exceptions in
18 the preceding sentence, the Secretary shall not
19 include as workload categories in forecasting
20 any non-core review activities, including any ac-
21 tivities that the Secretary referenced for poten-
22 tial future use in such notice but did not utilize
23 in setting fees for fiscal year 2021.’; and

24 (C) in subparagraph (C)—

1 (i) by striking “subsections (b)(2)(A)”
2 and inserting “subsections (b)(1)(A)”;

3 (ii) by striking “and (b)(2)(B)” and
4 inserting “, (b)(1)(B)”;

5 (iii) by inserting “, and (b)(1)(C) (the
6 dollar amount of the strategic hiring and
7 retention adjustment)” before the period at
8 the end;

9 (6) by amending paragraph (4), as so redesign-
10 nated, to read as follows:

11 “(4) OPERATING RESERVE ADJUSTMENT.—

12 “(A) INCREASE.—For fiscal year 2023 and
13 subsequent fiscal years, the Secretary shall, in
14 addition to adjustments under paragraphs (1),
15 (2), and (3), further increase the fee revenue
16 and fees if such an adjustment is necessary to
17 provide for at least 10 weeks of operating re-
18 serves of carryover user fees for the process for
19 the review of biosimilar biological product appli-
20 cations.

21 “(B) DECREASE.—

22 “(i) FISCAL YEAR 2023.—For fiscal
23 year 2023, if the Secretary has carryover
24 balances for the process for the review of
25 biosimilar biological product applications in

1 excess of 33 weeks of such operating re-
2 serves, the Secretary shall decrease such
3 fee revenue and fees to provide for not
4 more than 33 weeks of such operating re-
5 serves.

6 “(ii) FISCAL YEAR 2024.—For fiscal
7 year 2024, if the Secretary has carryover
8 balances for the process for the review of
9 biosimilar biological product applications in
10 excess of 27 weeks of such operating re-
11 serves, the Secretary shall decrease such
12 fee revenue and fees to provide for not
13 more than 27 weeks of such operating re-
14 serves.

15 “(iii) FISCAL YEAR 2025 AND SUBSE-
16 QUENT FISCAL YEAR.—For fiscal year
17 2025 and subsequent fiscal years, if the
18 Secretary has carryover balances for the
19 process for the review of biosimilar biologi-
20 cal product applications in excess of 21
21 weeks of such operating reserves, the Sec-
22 retary shall decrease such fee revenue and
23 fees to provide for not more than 21 weeks
24 of such operating reserves.

1 “(C) FEDERAL REGISTER NOTICE.—If an
2 adjustment under subparagraph (A) or (B) is
3 made, the rationale for the amount of the in-
4 crease or decrease (as applicable) in fee revenue
5 and fees shall be contained in the annual Fed-
6 eral Register notice under paragraph (5)(B) es-
7 tablishing fee revenue and fees for the fiscal
8 year involved.”; and

9 (7) in paragraph (5), in the matter preceding
10 subparagraph (A), by striking “2018” and inserting
11 “2023”.

12 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
13 tion 744H(f)(3) of the Federal Food, Drug, and Cosmetic
14 Act ((21 U.S.C. 379j–52(f)(3)) is amended by striking
15 “2018 through 2022” and inserting “2023 through
16 2027”.

17 (e) WRITTEN REQUESTS FOR WAIVERS AND RE-
18 FUNDS.—Subsection (h) of section 744H of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is
20 amended to read as follows:

21 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
22 TURNS; DISPUTES CONCERNING FEES.—To qualify for
23 consideration for a waiver under subsection (d), or the re-
24 turn of any fee paid under this section, including if the
25 fee is claimed to have been paid in error, a person shall

1 submit to the Secretary a written request justifying such
2 waiver or return and, except as otherwise specified in this
3 section, such written request shall be submitted to the Sec-
4 retary not later than 180 days after such fee is due. A
5 request submitted under this paragraph shall include any
6 legal authorities under which the request is made.”.

7 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

8 Section 744I of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 379j–53) is amended—

10 (1) by striking “2018” each place it appears
11 and inserting “2023”; and

12 (2) by striking “Biosimilar User Fee Amend-
13 ments of 2017” each place it appears and inserting
14 “Biosimilar User Fee Amendments of 2022”;

15 (3) in subsection (a)(4), by striking “2020” and
16 inserting “2023”; and

17 (4) in subsection (f), by striking “2022” each
18 place it appears and inserting “2027”.

19 **SEC. 405. SUNSET DATES.**

20 (a) AUTHORIZATION.—Sections 744G and 744H of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379j–51, 379j–52) shall cease to be effective October 1,
23 2027.

1 (b) REPORTING REQUIREMENTS.—Section 744I of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–53) shall cease to be effective January 31, 2028.

4 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
5 ber 1, 2022, subsections (a) and (b) of section 405 of the
6 FDA Reauthorization Act of 2017 (Public Law 115–52)
7 are repealed.

8 **SEC. 406. EFFECTIVE DATE.**

9 The amendments made by this title shall take effect
10 on October 1, 2022, or the date of the enactment of this
11 Act, whichever is later, except that fees under part 8 of
12 subchapter C of chapter VII of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be
14 assessed for all biosimilar biological product applications
15 received on or after October 1, 2022, regardless of the
16 date of the enactment of this Act.

17 **SEC. 407. SAVINGS CLAUSE.**

18 Notwithstanding the amendments made by this title,
19 part 8 of subchapter C of chapter VII of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as
21 in effect on the day before the date of the enactment of
22 this title, shall continue to be in effect with respect to bio-
23 similar biological product applications and supplements
24 (as defined in such part as of such day) that were accepted
25 by the Food and Drug Administration for filing on or after

1 October 1, 2017, but before October 1, 2022, with respect
2 to assessing and collecting any fee required by such part
3 for a fiscal year prior to fiscal year 2023.

4 **TITLE V—IMPROVING REGULA-**
5 **TION OF DRUGS AND BIO-**
6 **LOGICAL PRODUCTS**

7 **SEC. 501. ALTERNATIVES TO ANIMAL TESTING.**

8 (a) IN GENERAL.—Section 505 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

10 (1) in subsection (i)—

11 (A) in paragraph (1)(A), by striking “pre-
12 clinical tests (including tests on animals)” and
13 inserting “nonclinical tests or studies”; and

14 (B) in paragraph (2)(B), by striking “ani-
15 mal” and inserting “nonclinical tests or stud-
16 ies”; and

17 (2) after subsection (y), by inserting the fol-
18 lowing:

19 “(z) NONCLINICAL TEST OR STUDY DEFINED.—For
20 purposes of this section, the term ‘nonclinical test or
21 study’ means a test or study conducted in vitro, in silico,
22 or in chemico, or a non-human in vivo test that occurs
23 before or during the clinical trial phase of the investigation
24 of the safety and effectiveness of a drug, and may include
25 animal tests, or non-animal or human biology-based test

1 methods, such as cell-based assays, microphysiological sys-
2 tems, or computer models.”.

3 (b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
4 TIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the
5 Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I))
6 is amended to read as follows:

7 “(bb) an assessment of tox-
8 icity (which may rely on, or con-
9 sist of, a study or studies de-
10 scribed in item (aa) or (cc));
11 and”.

12 **SEC. 502. SAFER DISPOSAL OF OPIOIDS.**

13 Section 505–1(e)(4)(B) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 355–1(e)(4)(B)) is amended
15 by striking “for purposes of rendering drugs nonretriev-
16 able (as defined in section 1300.05 of title 21, Code of
17 Federal Regulations (or any successor regulation))”.

18 **SEC. 503. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS**
19 **FOR FIRST INTERCHANGEABLE BIOSIMILAR**
20 **BIOLOGICAL PRODUCTS.**

21 Section 351(k)(6) of the Public Health Service Act
22 (42 U.S.C. 262(k)(6)) is amended—

23 (1) in the matter preceding subparagraph (A)—

1 (A) by striking “Upon review of” and in-
2 serting “The Secretary shall not make approval
3 effective of”;

4 (B) by striking “relying on” and inserting
5 “for an interchangeable biological product that
6 relies on”; and

7 (C) by striking “the Secretary shall not
8 make a determination under paragraph (4) that
9 the second or subsequent biological product is
10 interchangeable for any condition of use”; and

11 (2) in the flush text that follows subparagraph
12 (C), by striking the period and inserting “, and the
13 term ‘first interchangeable biosimilar biological prod-
14 uct’ means any interchangeable biosimilar biological
15 product that is approved on the first day on which
16 such a product is approved as interchangeable with
17 the reference product.”.

18 **SEC. 504. IMPROVEMENTS TO THE PURPLE BOOK.**

19 (a) IN GENERAL.—Section 506I of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

21 (1) in subsection (a)—

22 (A) by striking “The holder of an applica-
23 tion approved under subsection (c) or (j) of sec-
24 tion 505” and inserting “The holder of an ap-
25 plication approved under subsection (c) or (j) of

1 section 505 of this Act or subsection (a) or (k)
2 of section 351 of the Public Health Service
3 Act”;

4 (B) in paragraph (2), by inserting “(or, in
5 the case of a biological product, the proper
6 name)” after “established name”;

7 (C) in paragraph (3), by striking “or ab-
8 breviated application number” and inserting “,
9 abbreviated application number, or biologics li-
10 cense application number”; and

11 (2) in subsection (b)—

12 (A) in the matter preceding paragraph (1),
13 by striking “The holder of an application ap-
14 proved under subsection (c) or (j)” and insert-
15 ing “The holder of an application approved
16 under subsection (c) or (j) of section 505 of
17 this Act or subsection (a) or (k) of section 351
18 of the Public Health Service Act”;

19 (B) in paragraph (1), by inserting “(or, in
20 the case of a biological product, the proper
21 name)” after “established name”; and

22 (C) in paragraph (2), by striking “or ab-
23 breviated application number” and inserting “,
24 abbreviated application number, or biologics li-
25 cense application number”.

1 (b) ADDITIONAL ONE-TIME REPORT.—Subsection
2 (c) of section 506I of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 356i) is amended to read as follows:

4 “(c) ADDITIONAL ONE-TIME REPORT.—Within 180
5 days of the date of enactment of the Food and Drug Ad-
6 ministration Safety and Landmark Advancements Act of
7 2022, all holders of applications approved under sub-
8 section (a) or (k) of section 351 of the Public Health Serv-
9 ice Act shall review the information in the list published
10 under section 351(k)(9)(A) and shall submit a written no-
11 tice to the Secretary—

12 “(1) stating that all of the application holder’s
13 biological products in the list published under sec-
14 tion 351(k)(9)(A) that are not listed as discontinued
15 are available for sale; or

16 “(2) including the information required pursu-
17 ant to subsection (a) or (b), as applicable, for each
18 of the application holder’s biological products that
19 are in the list published under section 351(k)(9)(A)
20 and not listed as discontinued, but have been discon-
21 tinued from sale or never have been available for
22 sale.”.

23 (c) PURPLE BOOK.—Section 506I of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
25 ed—

1 (1) in subsection (d)—

2 (A) by striking “or (c), the Secretary” and

3 inserting “or (c)—

4 “(1) the Secretary”;

5 (B) by striking the period at the end, and

6 inserting “; and”; and

7 (C) by adding at the end the following:

8 “(2) the Secretary may identify the application
9 holder’s biological products as discontinued in the
10 list published under section 351(k)(9)(A) of the
11 Public Health Service Act, except that the Secretary
12 shall remove from the list in accordance with section
13 351(k)(9)(B) of such Act any biological product for
14 which a license has been revoked or suspended for
15 reasons of safety, purity, or potency.”; and

16 (2) in subsection (e)—

17 (A) by inserting after the first sentence the
18 following: “The Secretary shall update the list
19 published under section 351(k)(9)(A) of the
20 Public Health Service Act based on information
21 provided under subsections (a), (b), and (c) by
22 identifying as discontinued biological products
23 that are not available for sale, except that any
24 biological product for which the license has been
25 revoked or suspended for reasons of safety, pu-

1 rity, or potency shall be removed from the list
2 in accordance with section 351(k)(9)(B) of the
3 Public Health Service Act.”; and

4 (B) in the last sentence—

5 (i) by striking “updates to the list”
6 and inserting “updates to the lists pub-
7 lished under section 505(j)(7)(A) of this
8 Act and section 351(k)(9)(A) of the Public
9 Health Service Act”; and

10 (ii) by striking “update the list” and
11 inserting “update such lists”.

12 **TITLE VI—OTHER**
13 **REAUTHORIZATIONS**

14 **SEC. 601. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
15 **LIC-PRIVATE PARTNERSHIP.**

16 Section 566(f) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
18 “2018 through 2022” and inserting “2023 through
19 2027”.

20 **SEC. 602. REAUTHORIZATION OF THE BEST PHARMA-**
21 **CEUTICALS FOR CHILDREN PROGRAM.**

22 Section 409I(d)(1) of the Public Health Service Act
23 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
24 through 2022” and inserting “2023 through 2027”.

1 **SEC. 603. REAUTHORIZATION OF THE HUMANITARIAN DE-**
2 **VICE EXEMPTION INCENTIVE.**

3 Section 520(m)(6)(A)(iv) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
5 amended by striking “2022” and inserting “2027”.

6 **SEC. 604. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
7 **CONSORTIA PROGRAM.**

8 Section 305(e) of the Food and Drug Administration
9 Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.
10 282 note) is amended by striking “\$5,250,000 for each
11 of fiscal years 2018 through 2022” and inserting
12 “\$7,000,000 for each of fiscal years 2023 through 2027”.

13 **SEC. 605. REAUTHORIZATION OF PROVISION PERTAINING**
14 **TO DRUGS CONTAINING SINGLE**
15 **ENANTIOMERS.**

16 Section 505(u)(4) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
18 ing “October 1, 2022” and inserting “October 1, 2027”.

19 **SEC. 606. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

20 Section 5(c) of the Orphan Drug Act (21 U.S.C.
21 360ee(c)) is amended by striking “2018 through 2022”
22 and inserting “2023 through 2027”.

1 **TITLE VII—ENHANCING FDA**
2 **HIRING AUTHORITIES**

3 **SEC. 701. ENHANCING FDA HIRING AUTHORITY FOR SCI-**
4 **ENTIFIC, TECHNICAL, AND PROFESSIONAL**
5 **PERSONNEL.**

6 Section 714A of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 379d–3a) is amended—

8 (1) in subsection (a)—

9 (A) by inserting “, including cross-cutting
10 operational positions,” after “professional posi-
11 tions”; and

12 (B) by inserting “and the regulation of
13 food” after “medical products”; and

14 (2) in subsection (d)(1)—

15 (A) in the matter preceding subparagraph

16 (A)—

17 (i) by striking “the 21st Century
18 Cures Act” and inserting “the Food and
19 Drug Administration Safety and Land-
20 mark Advancements Act of 2022”; and

21 (ii) by striking “that examines the ex-
22 tent” and all that follows through “, in-
23 cluding” and inserting “that addresses”;

24 (B) in subparagraph (A)—

1 (i) by inserting “updated” before
2 “analysis”; and

3 (ii) by striking “; and” and inserting
4 a semicolon;

5 (C) by redesignating subparagraph (B) as
6 subparagraph (C);

7 (D) by inserting after subparagraph (A)
8 the following:

9 “(B) an analysis of how the Secretary has
10 used the authorities provided under this section,
11 and a plan for how the Secretary will use the
12 authority under this section, and other applica-
13 ble hiring authorities, for employees of the
14 Food and Drug Administration; and”;

15 (E) in subparagraph (C), as so redesign-
16 ated, by striking “a recruitment” and insert-
17 ing “an updated recruitment”.

18 **SEC. 702. STRATEGIC WORKFORCE PLAN AND REPORT.**

19 Chapter VII of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 371 et seq.) is amended by inserting
21 after section 714A the following:

22 **“SEC. 714B. STRATEGIC WORKFORCE PLAN AND REPORT.**

23 “(a) IN GENERAL.—Not later than September 30,
24 2023, and at least every 4 years thereafter, the Secretary
25 shall develop and submit to the appropriate committees

1 of Congress and post on the website of the Food and Drug
2 Administration, a coordinated strategy and report to pro-
3 vide direction for the activities and programs of the Sec-
4 retary to recruit, hire, train, develop, and retain the work-
5 force needed to fulfill the public health mission of the
6 Food and Drug Administration, including to facilitate col-
7 laboration across centers, to keep pace with new bio-
8 medical, technological, and scientific advancements, and
9 support the development, review, and regulation of med-
10 ical products. Each such report shall be known as the
11 ‘Food and Drug Administration Strategic Workforce
12 Plan’.

13 “(b) USE OF THE FOOD AND DRUG ADMINISTRATION
14 STRATEGIC WORKFORCE PLAN.—Each center within the
15 Food and Drug Administration shall develop and update,
16 as appropriate, a strategic plan that will be informed by
17 the Food and Drug Administration Strategic Workforce
18 Plan developed and updated under this subsection.

19 “(c) CONTENTS OF THE FOOD AND DRUG ADMINIS-
20 TRATION STRATEGIC WORKFORCE PLAN.—Each Food
21 and Drug Administration Strategic Workforce Plan under
22 subsection (a) shall—

23 “(1) include agency-wide strategic goals and
24 priorities for recruiting, hiring, training, developing,

1 and retaining a qualified workforce for the Food and
2 Drug Administration;

3 “(2) establish specific activities the Secretary
4 will take to achieve its strategic goals and priorities
5 and address the workforce needs of the Food and
6 Drug Administration in the forthcoming fiscal years;

7 “(3) identify challenges and risks the Secretary
8 will face in meeting its strategic goals and priorities,
9 and the activities the Secretary will undertake to
10 overcome those challenges and mitigate those risks;

11 “(4) establish metrics and milestones that the
12 Secretary will use to measure progress in achieving
13 its strategic goals and priorities; and

14 “(5) define functions, capabilities, and gaps in
15 such workforce and identify strategies to recruit,
16 hire, train, develop, and retain such workforce.

17 “(d) CONSIDERATIONS.—In developing each Food
18 and Drug Administration Strategic Workforce Plan under
19 subsection (a), the Secretary shall consider—

20 “(1) the number of employees, employee exper-
21 tise, and employing center of employees, including
22 senior leadership and non-senior leadership employ-
23 ees, eligible for retirement;

24 “(2) the vacancy and turnover rates for employ-
25 ees with different types of expertise and from dif-

1 ferent centers, including any changes or trends re-
2 lated to such rates;

3 “(3) the results of the Federal Employee View-
4 point Survey for employees of the Food and Drug
5 Administration, including any changes or trends re-
6 lated to such results;

7 “(4) rates of pay for different types of posi-
8 tions, including rates for different types of expertise
9 within the same field (such as differences in pay be-
10 tween different medical specialists), and how such
11 rates of pay impact the ability of the Secretary to
12 achieve strategic goals and priorities; and

13 “(5) the statutory hiring authorities used to
14 hire Food and Drug Administration employees, and
15 the time to hire across different hiring authorities.

16 “(e) EVALUATION OF PROGRESS.—Each Food and
17 Drug Administration Strategic Workforce Plan issued
18 pursuant to subsection (a), with the exception of the first
19 such Food and Drug Administration Strategic Workforce
20 Plan, shall include an evaluation of the progress the Sec-
21 retary has made, based on the metrics, benchmarks, and
22 other milestones that measure successful recruitment, hir-
23 ing, training, development, and retention activities; and
24 whether such actions improved the capacity of the Food
25 and Drug Administration to achieve the strategic goals

1 and priorities set forth in the previous Food and Drug
2 Administration Strategic Workforce Plan.

3 “(f) **ADDITIONAL CONSIDERATIONS.**—The Food and
4 Drug Administration Strategic Workforce Plan issued in
5 fiscal year 2023 shall address the effect of the COVID–
6 19 pandemic on hiring, retention, and other workforce
7 challenges for the Food and Drug Administration, includ-
8 ing protecting such workforce during public health emer-
9 gencies.”.

10 **TITLE VIII—ADVANCING REGU-**
11 **LATION OF COSMETICS, DIE-**
12 **TARY SUPPLEMENTS, AND**
13 **LABORATORY DEVELOPED**
14 **TESTS**

15 **Subtitle A—Cosmetics**

16 **SEC. 801. SHORT TITLE.**

17 This subtitle may be cited as the “Modernization of
18 Cosmetics Regulation Act of 2022”.

19 **SEC. 802. AMENDMENTS TO COSMETIC REQUIREMENTS.**

20 Chapter VI of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 361 et seq.) is amended by adding at the
22 end the following:

23 **“SEC. 604. DEFINITIONS.**

24 “In this chapter:

1 “(1) ADVERSE EVENT.—The term ‘adverse
2 event’ means any health-related event associated
3 with the use of a cosmetic product that is adverse.

4 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
5 product’ means a preparation of cosmetic ingredi-
6 ents with a qualitatively and quantitatively set com-
7 position for use in a finished product.

8 “(3) FACILITY.—

9 “(A) IN GENERAL.—The term ‘facility’ in-
10 cludes any establishment (including an estab-
11 lishment of an importer) that manufactures or
12 processes cosmetic products distributed in the
13 United States.

14 “(B) Such term does not include any of
15 the following:

16 “(i) Beauty shops and salons, unless
17 such establishment manufactures or proc-
18 esses cosmetic products at that location.

19 “(ii) Cosmetic product retailers, in-
20 cluding individual sales representatives, re-
21 tail distribution facilities, and pharmacies,
22 unless such establishment manufactures or
23 processes cosmetic products that are not
24 sold directly to consumers at that location.

1 “(iii) Hospitals, physicians’ offices,
2 and health care clinics.

3 “(iv) Public health agencies and other
4 nonprofit entities that provide cosmetic
5 products directly to the consumer.

6 **【“(v) Entities that provide com-
7 plimentary cosmetic products.】**

8 “(vi) Trade shows and other venues
9 where cosmetic product samples are pro-
10 vided free of charge.

11 “(vii) An establishment that manufac-
12 tures or processes cosmetic products that
13 are solely for use in research or evaluation,
14 including for production testing and not of-
15 fered for retail sale.

16 “(viii) An establishment that solely
17 performs one or more of the following with
18 respect to cosmetic products:

19 “(I) Labeling.

20 “(II) Relabeling.

21 “(III) Packaging.

22 “(IV) Repackaging.

23 “(V) Holding.

24 “(VI) Distributing.

1 “(C) CLARIFICATION.—For the purposes
2 of subparagraph (B)(viii), the terms ‘packaging’
3 and ‘repackaging’ do not include filling a prod-
4 uct container with a cosmetic product.

5 “(4) RESPONSIBLE PERSON.—The term ‘re-
6 sponsible person’ means the manufacturer, packer,
7 or distributor of a cosmetic product whose name ap-
8 pears on the label of such cosmetic product in ac-
9 cordance with section 609(a) of this Act or section
10 4(a) of the Fair Packaging and Labeling Act.

11 “(5) SERIOUS ADVERSE EVENT.—The term ‘se-
12 rious adverse event’ means an adverse event that—

13 “(A) results in—

14 “(i) death;

15 “(ii) a life-threatening experience;

16 “(iii) inpatient hospitalization;

17 “(iv) a persistent or significant dis-
18 ability or incapacity;

19 “(v) a congenital anomaly or birth de-
20 fect; or

21 “(vi) significant disfigurement (includ-
22 ing serious and persistent rashes or infec-
23 tions, second- or third-degree burns, sig-
24 nificant hair loss, or permanent or signifi-
25 cant alteration of appearance), other than

1 as intended, under conditions of use that
2 are customary or usual; or

3 “(B) requires, based on reasonable medical
4 judgment, a medical or surgical intervention to
5 prevent an outcome described in subparagraph
6 (A).

7 **“SEC. 605. ADVERSE EVENTS.**

8 “(a) ADVERSE EVENT REPORTING REQUIRE-
9 MENTS.—

10 “(1) IN GENERAL.—The responsible person
11 shall submit to the Secretary any report received of
12 a serious adverse event associated with the use, in
13 the United States, of a cosmetic product manufac-
14 tured, packed, or distributed by such person.

15 “(b) SUBMISSION OF REPORTS.—

16 “(1) SERIOUS ADVERSE EVENT REPORT.—The
17 responsible person shall submit to the Secretary a
18 serious adverse event report accompanied by a copy
19 of the label on or within the retail packaging of such
20 cosmetic product no later than 15 business days
21 after the report is received by the responsible per-
22 son.

23 “(2) NEW MEDICAL INFORMATION.—The re-
24 sponsible person shall submit to the Secretary any
25 new and material medical information, related to a

1 serious adverse event report submitted to the Sec-
2 retary in accordance with paragraph (1), that is re-
3 ceived by the responsible person within 1 year of the
4 initial report to the Secretary, no later than 15 busi-
5 ness days after such information is received by such
6 responsible person.

7 “(3) CONSOLIDATION OF REPORTS.—The Sec-
8 retary shall develop systems to enable responsible
9 persons to submit a single report that includes du-
10 plicate reports of, or new medical information re-
11 lated to, a serious adverse event.

12 “(c) EXEMPTIONS.—The Secretary may establish by
13 regulation an exemption to any of the requirements of this
14 section if the Secretary determines that such exemption
15 would have no significant adverse effect on public health.

16 “(d) CONTACT INFORMATION.—The responsible per-
17 son shall receive reports of adverse events through the do-
18 mestic address, domestic telephone number, or electronic
19 contact information included on the label in accordance
20 with section 609(a).

21 “(e) MAINTENANCE AND INSPECTION OF ADVERSE
22 EVENT RECORDS.—

23 “(1) MAINTENANCE.—The responsible person
24 shall maintain records related to each report of an
25 adverse event associated with the use, in the United

1 States, of a cosmetic product manufactured or dis-
2 tributed by such person received by such person, for
3 a period of 6 years.

4 “(2) INSPECTION.—

5 “(A) IN GENERAL.— The responsible per-
6 son shall permit an authorized person to have
7 access to records required to be maintained
8 under this section during an inspection pursu-
9 ant to section 704.

10 “(B) AUTHORIZED PERSON.—For pur-
11 poses of this paragraph, the term ‘authorized
12 person’ means an officer or employee of the De-
13 partment of Health and Human Services who
14 has—

15 “(i) appropriate credentials, as deter-
16 mined by the Secretary; and

17 “(ii) been duly designated by the Sec-
18 retary to have access to the records re-
19 quired under this section.

20 “(f) FRAGRANCE AND FLAVOR INGREDIENTS.—If
21 the Secretary has reasonable grounds to believe that an
22 ingredient or combination of ingredients in a fragrance or
23 flavor has caused a serious adverse event required to be
24 reported under this section, the Secretary may request in
25 writing a complete list of ingredients in the specific fra-

1 grances or flavors in the cosmetic product, from the re-
2 sponsible person. The responsible person shall ensure that
3 the requested information is submitted to the Secretary
4 within 30 days of such request.

5 “(g) PROTECTED INFORMATION.—A serious adverse
6 event report submitted to the Secretary under this section,
7 including any new medical information submitted under
8 subsection (a)(2), or an adverse event report, or any new
9 information, voluntarily submitted to the Secretary shall
10 be considered to be—

11 “(1) a safety report under section 756 and may
12 be accompanied by a statement, which shall be a
13 part of any report that is released for public disclo-
14 sure, that denies that the report or the records con-
15 stitute an admission that the product involved
16 caused or contributed to the adverse event; and

17 “(2) a record about an individual under section
18 552a of title 5, United States Code (commonly re-
19 ferred to as the ‘Privacy Act of 1974’) and a med-
20 ical or similar file the disclosure of which would con-
21 stitute a violation of section 552 of such title 5
22 (commonly referred to as the ‘Freedom of Informa-
23 tion Act’), and shall not be publicly disclosed unless
24 all personally identifiable information is redacted.

25 “(h) EFFECT OF SECTION.—

1 “(1) IN GENERAL.—Nothing in this section
2 shall affect the authority of the Secretary to provide
3 adverse event reports and information to any health,
4 food, or drug officer or employee of any State, terri-
5 tory, or political subdivision of a State or territory,
6 under a memorandum of understanding between the
7 Secretary and such State, territory, or political sub-
8 division.

9 “(2) PERSONALLY IDENTIFIABLE INFORMA-
10 TION.—Notwithstanding any other provision of law,
11 personally-identifiable information in adverse event
12 reports provided by the Secretary to any health,
13 food, or drug officer or employee of any State, terri-
14 tory, or political subdivision of a State or territory,
15 shall not—

16 “(A) be made publicly available pursuant
17 to any State or other law requiring disclosure
18 of information or records; or

19 “(B) otherwise be disclosed or distributed
20 to any party without the written consent of the
21 Secretary and the person submitting such infor-
22 mation to the Secretary.

23 “(3) USE OF REPORTS.—Nothing in this sec-
24 tion shall permit a State, territory, or political sub-
25 division of a State or territory, to use any safety re-

1 port received from the Secretary in a manner incon-
2 sistent with this section.

3 “(4) **RULE OF CONSTRUCTION.**—The submis-
4 sion of any report in compliance with this section
5 shall not be construed as an admission that the cos-
6 metic product involved caused or contributed to the
7 relevant adverse event.”.

8 **“SEC. 606. GOOD MANUFACTURING PRACTICE.**

9 “(a) **IN GENERAL.**—The Secretary shall by regula-
10 tion establish good manufacturing practices for facilities
11 that are consistent, to the extent practicable, and appro-
12 priate, with national and international standards, in ac-
13 cordance with section 601. Any such regulations shall be
14 intended to protect the public health and ensure that cos-
15 metic products are not adulterated. Such regulations may
16 allow for the Secretary to inspect records necessary to
17 demonstrate compliance with good manufacturing prac-
18 tices prescribed by the Secretary under this paragraph
19 during an inspection conducted under section 704.

20 “(b) **CONSIDERATIONS.**—In establishing regulations
21 for good manufacturing practices under this section, the
22 Secretary shall take into account the size and scope of the
23 businesses engaged in the manufacture of cosmetics, and
24 the risks to public health posed by such cosmetics, and
25 provide sufficient flexibility to be practicable for all sizes

1 and types of facilities to which such regulations will apply.
2 Such regulations shall include simplified good manufac-
3 turing practice requirements for smaller businesses, as ap-
4 propriate, to ensure that such regulations do not impose
5 undue economic hardship for smaller businesses, and may
6 include longer compliance times for smaller businesses.
7 Before issuing regulations to implement subsection (a),
8 the Secretary shall consult with cosmetics manufacturers,
9 including smaller businesses, consumer organizations, and
10 other experts selected by the Secretary.

11 “(c) TIMEFRAME.—The Secretary shall publish a no-
12 tice of proposed rulemaking not later than 2 years after
13 the date of enactment of the Modernization of Cosmetics
14 Regulation Act of 2022 and shall publish a final such rule
15 not later than 3 years after such date of enactment.

16 **“SEC. 607. REGISTRATION AND PRODUCT LISTING.**

17 “(a) SUBMISSION OF REGISTRATION.—

18 “(1) INITIAL REGISTRATION.—

19 “(A) EXISTING FACILITIES.—Every person
20 that owns or operates a facility, on the date of
21 enactment of the Modernization of Cosmetics
22 Regulation Act of 2022, shall register each fa-
23 cility with the Secretary not later than 1 year
24 after date of enactment of such Act.

1 “(B) NEW FACILITIES.—Every person that
2 owns or operates a facility that first engages,
3 after the date of enactment of the Moderniza-
4 tion of Cosmetics Regulation Act of 2022, in
5 manufacturing or processing of a cosmetic
6 product for distribution in the United States,
7 shall register with the Secretary such facility
8 within 60 days of first engaging in such activity
9 or 60 days after the deadline for registration
10 under clause (A), whichever is later.

11 “(2) BIENNIAL RENEWAL OF REGISTRATION.—
12 Every person required to register a facility under
13 paragraph (1) shall renew such registrations with
14 the Secretary biennially.

15 **【“(3) CONTRACT MANUFACTURERS.—If a facil-**
16 **ity manufactures or processes cosmetic products on**
17 **behalf of a responsible person, the Secretary shall**
18 **require only a single registration for such facility**
19 **even if such facility is manufacturing or processing**
20 **its own cosmetic products or cosmetic products on**
21 **behalf of more than one responsible person. Such**
22 **single registration may be submitted to the Sec-**
23 **retary by such facility or any responsible person**
24 **whose products are manufactured or processed at**
25 **such facility.】**

1 “(4) UPDATES TO CONTENT.—A person that is
2 required to register under subsection (a)(1) shall no-
3 tify the Secretary within 60 days of any changes to
4 information required under subsection (b)(2).

5 “(5) ABBREVIATED RENEWAL REGISTRA-
6 TIONS.—The Secretary shall provide for an abbrevi-
7 ated registration renewal process for any person
8 that owns or operates a facility that has not been re-
9 quired to submit updates under paragraph (4) for a
10 registered facility since submission of the most re-
11 cent registration of such facility under paragraph
12 (1) or (2).

13 “(b) FORMAT; CONTENTS OF REGISTRATION.—

14 “(1) IN GENERAL.—Registration information
15 under this section may be submitted at such time
16 and in such manner as the Secretary may prescribe.

17 “(2) CONTENTS.—The registration under sub-
18 section (a) shall contain—

19 “(A) the facility’s name, physical address,
20 email address, and telephone number;

21 “(B) with respect to any foreign facility,
22 the contact for the United States agent of the
23 facility, and, if available, the electronic contact
24 information;

1 “(C) the facility registration number, if
2 any, previously assigned by the Secretary under
3 subsection (d);

4 “(D) all brand names under which cos-
5 metic products manufactured or processed in
6 the facility are sold; and

7 “(E) the product category or categories
8 and responsible person for each cosmetic prod-
9 uct manufactured or processed at the facility.

10 “(c) COSMETIC PRODUCT LISTING.—

11 “(1) IN GENERAL.—For each cosmetic product,
12 the responsible person shall submit, or ensure is sub-
13 mitted, to the Secretary a cosmetic product listing,
14 at such time and in such manner as the Secretary
15 may prescribe.

16 “(2) COSMETIC PRODUCT LISTING.—The re-
17 sponsible person of a cosmetic product that is mar-
18 keted on the date of enactment of the Modernization
19 of Cosmetics Regulation Act of 2022 shall submit to
20 the Secretary a cosmetic product listing not later
21 than 1 year after the date of enactment of the Mod-
22 ernization of Cosmetics Regulation Act of 2022, or
23 for a cosmetic product that is first marketed after
24 the date of enactment of such Act, within 120 days
25 of marketing such product in interstate commerce.

1 Thereafter, any updates to such listing shall be
2 made annually, consistent with paragraphs (4) and
3 (5).

4 “(3) ABBREVIATED RENEWAL.—The Secretary
5 shall provide for an abbreviated process for the re-
6 newal of any cosmetic product listing under this sub-
7 section with respect to which there has been no
8 change since the responsible person submitted the
9 previous listing.

10 “(4) CONTENTS OF LISTING.—

11 “(A) IN GENERAL.—Each such cosmetic
12 product listing shall include—

13 “(i) the facility registration number of
14 each facility where the cosmetic product is
15 manufactured or processed;

16 “(ii) the name and contact number of
17 the responsible person and the name for
18 the cosmetic product, as such name ap-
19 pears on the label;

20 “(iii) the applicable cosmetic category
21 or categories for the cosmetic product;

22 “(iv) a list of ingredients in the cos-
23 metic product, including any fragrances,
24 flavors, or colors, with each ingredient
25 identified by the name adopted in regula-

1 tions promulgated by the Secretary, if any,
2 or by the common or usual name of the in-
3 gredient; and

4 “(v) the product listing number, if
5 any previously assigned by the Secretary
6 under subsection (d).

7 “(B) FORMULATIONS.—A single listing
8 submission for a cosmetic product may include
9 multiple cosmetic products with identical formu-
10 lations, or formulations that differ only with re-
11 spect to colors, fragrances or flavors, or quan-
12 tity of contents.

13 “(5) UPDATES TO CONTENT.—A responsible
14 person that is required to submit a cosmetic product
15 listing shall submit any updates to such cosmetic
16 product listing annually.

17 “(6) SUBMISSION.—A responsible person may
18 submit product listing information as part of a reg-
19 istration or separately.

20 “(d) FACILITY REGISTRATION AND PRODUCT LIST-
21 ING NUMBERS.—At the time of the initial registration of
22 any facility under subsection (a)(1) or initial listing of any
23 cosmetic product under (c)(1), the Secretary shall assign
24 a facility registration number to the facility and a product
25 listing number to each cosmetic product. The Secretary

1 shall not make such product listing number publicly avail-
2 able.

3 “(e) CONFIDENTIALITY.—Information submitted
4 under subsection (c)(4)(A)(i) shall be considered confiden-
5 tial commercial information.

6 “(f) SUSPENSIONS.—

7 “(1) SUSPENSION OF REGISTRATION OF A FA-
8 CILITY.—The Secretary may suspend the registra-
9 tion of a facility if the Secretary determines that a
10 cosmetic product manufactured or processed by a
11 registered facility and distributed in the United
12 States has a reasonable probability of causing seri-
13 ous adverse health consequences or death to humans
14 and the Secretary has a reasonable belief that other
15 products manufactured or processed by the facility
16 may be similarly affected because of a failure that
17 cannot be isolated to a product or products, or is
18 sufficiently pervasive to raise concerns about other
19 products manufactured in the facility.

20 “(2) NOTICE OF SUSPENSION.—Before sus-
21 pending a facility registration under this section, the
22 Secretary shall provide—

23 “(A) notice to the facility registrant of the
24 cosmetic product or other responsible person, as
25 appropriate, of the intent to suspend the facility

1 registration, which shall specify the basis of the
2 determination by the Secretary that the facility
3 should be suspended and recommendations for
4 specific actions to avoid suspension; and

5 “(B) an opportunity, within 5 business
6 days of the notice provided under subparagraph
7 (A), for the responsible person to provide a plan
8 for addressing the reasons for possible suspen-
9 sion of the facility registration.

10 “(3) HEARING ON SUSPENSION.—The Secretary
11 shall provide the registrant subject to an order
12 under paragraph (1) or (2) with an opportunity for
13 an informal hearing, to be held as soon as possible
14 but not later than 5 business days after the issuance
15 of the order, or such other time period agreed upon
16 by the Secretary and the registrant, on the actions
17 required for reinstatement of registration and why
18 the registration that is subject to the suspension
19 should be reinstated. The Secretary shall reinstate a
20 registration if the Secretary determines, based on
21 evidence presented, that adequate grounds do not
22 exist to continue the suspension of the registration.

23 “(4) POST-HEARING CORRECTIVE ACTION
24 PLAN.—If, after providing opportunity for an infor-
25 mal hearing under paragraph (3), the Secretary de-

1 termines that the suspension of registration remains
2 necessary, the Secretary shall require the registrant
3 to submit a corrective action plan to demonstrate
4 how the registrant plans to correct the conditions
5 found by the Secretary. The Secretary shall review
6 such plan not later than 14 business days after the
7 submission of the corrective action plan or such
8 other time period as determined by the Secretary, in
9 consultation with the registrant.

10 “(5) VACATING OF ORDER; REINSTATEMENT.—

11 Upon a determination by the Secretary that ade-
12 quate grounds do not exist to continue the suspen-
13 sion actions, the Secretary shall promptly vacate the
14 suspension and reinstate the registration of the facil-
15 ity.

16 “(6) EFFECT OF SUSPENSION.—If the registra-

17 tion of the facility is suspended under this section,
18 no person shall introduce or deliver for introduction
19 into interstate commerce cosmetic formulations or
20 products from such facility.

21 “(7) NO DELEGATION.—The authority con-

22 ferred by this section to issue an order to suspend
23 a registration or vacate an order of suspension shall
24 not be delegated to any officer or employee other
25 than the Commissioner.

1 **“SEC. 608. SAFETY SUBSTANTIATION.**

2 “(a) SUBSTANTIATION OF SAFETY.—A responsible
3 person for a cosmetic product shall ensure【, and maintain
4 records supporting,】 that there is adequate substantiation
5 of safety of such cosmetic product.

6 “(b) COAL TAR HAIR DYE.—This section shall not
7 apply to coal-tar hair dye that otherwise complies with the
8 requirements of section 601(a).

9 “(c) DEFINITIONS.—For purposes of this section:

10 “(1) ADEQUATE SUBSTANTIATION OF SAFE-
11 TY.—The term ‘adequate substantiation of safety’
12 means tests or studies, research, analyses, or other
13 evidence or information that is considered, among
14 experts qualified by scientific training and experi-
15 ence to evaluate the safety of cosmetic products and
16 their ingredients, sufficient to support a reasonable
17 certainty that a cosmetic product is safe.

18 “(2) SAFE.—The term ‘safe’ means that the
19 cosmetic product, including any ingredient thereof,
20 is not injurious to users under the conditions of use
21 prescribed in the labeling thereof, or under such con-
22 ditions of use as are customary or usual. The Sec-
23 retary shall not consider a cosmetic ingredient or
24 cosmetic product injurious to users solely because it
25 can cause minor and transient reactions or minor
26 and transient skin irritations in some users. 【In de-

1 termining for purposes of this section whether a cos-
2 metic product is safe, the Secretary may consider, as
3 appropriate and available, the cumulative or other
4 relevant exposure to the cosmetic product, including
5 any ingredient thereof.】

6 **“SEC. 609. LABELING.**

7 “(a) GENERAL REQUIREMENT.—Each cosmetic prod-
8 uct shall bear a label that includes a domestic address,
9 domestic phone number, or electronic contact information
10 through which the responsible person can receive adverse
11 event reports with respect to such cosmetic product.

12 “(b) FRAGRANCE ALLERGENS.—The responsible per-
13 son shall identify on the label of a cosmetic product each
14 fragrance allergen included in such cosmetic product. Sub-
15 stances that are fragrance allergens for purposes of this
16 subsection shall be determined by the Secretary by regula-
17 tion. The Secretary shall issue a notice of proposed rule-
18 making promulgating the regulation implementing this re-
19 quirement not later than one year after enactment of the
20 Modernization of Cosmetics Regulation Act of 2022. In
21 promulgating a regulation implementing this requirement,
22 the Secretary shall consider international, state, and local
23 requirements for allergen disclosure, including require-
24 ments in the European Union.

1 “(c) COSMETIC PRODUCTS FOR PROFESSIONAL
2 USE.—

3 “(1) DEFINITION OF PROFESSIONAL.—For pur-
4 poses of this subsection, the term ‘professional’
5 means an individual who is licensed by an official
6 State authority to practice in the field of cosme-
7 tology, nail care, barbering, or esthetics.

8 “(2) PROFESSIONAL USE LABELING.—A cos-
9 metic product introduced into interstate commerce
10 and intended to be used only by a professional shall
11 bear a label that—

12 “(A) contains a clear and prominent state-
13 ment that the product shall be administered or
14 used only by licensed professionals; and

15 “(B) is in conformity with the require-
16 ments of the Secretary under this Act and sec-
17 tion 4(a) of the Fair Packaging and Labeling
18 Act.

19 **“SEC. 610. RECORDS.**

20 “(a) IN GENERAL.—If the Secretary has a reasonable
21 belief that a cosmetic product, including an ingredient in
22 such cosmetic product, and any other cosmetic product
23 that the Secretary reasonably believes is likely to be af-
24 fected in a similar manner, is likely to be adulterated such
25 that the use or exposure to such product presents a threat

1 of serious adverse health consequences or death to hu-
2 mans, each responsible person and facility shall, at the re-
3 quest of an officer or employee duly designated by the Sec-
4 retary, permit such officer or employee, upon presentation
5 of appropriate credentials and a written notice to such
6 person, at reasonable times and within reasonable limits
7 and in a reasonable manner, to have access to and copy
8 all records relating to such cosmetic product, and to any
9 other cosmetic product that the Secretary reasonably be-
10 lieves is likely to be affected in a similar manner, that
11 are needed to assist the Secretary in determining whether
12 the cosmetic product is adulterated and presents a threat
13 of serious adverse health consequences or death to hu-
14 mans. This subsection shall not be construed to extend
15 to recipes [or formulas] for cosmetics, financial data,
16 pricing data, personnel data (other than data as to quali-
17 fication of technical and professional personnel performing
18 functions subject to this Act), research data (other than
19 safety substantiation data), or sales data (other than ship-
20 ment data regarding sales).

21 “(b) PROTECTION OF SENSITIVE INFORMATION.—
22 The Secretary shall take appropriate measures to ensure
23 that there are in effect effective procedures to prevent the
24 unauthorized disclosure of any trade secret or confidential

1 information that is obtained by the Secretary pursuant to
2 this section.

3 “(c) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed to affect section 605 or 606 with
5 respect to access to records.

6 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

7 “(a) **IN GENERAL.**—If the Secretary determines that
8 there is a reasonable probability that a cosmetic is adulter-
9 ated under section 601 or misbranded under section 602
10 and the use of or exposure to such cosmetic will cause
11 serious adverse health consequences or death, the Sec-
12 retary shall provide the responsible person with an oppor-
13 tunity to voluntarily cease distribution and recall such ar-
14 ticle. If the responsible person refuses to or does not vol-
15 untarily cease distribution or recall such cosmetic within
16 the time and manner prescribed by the Secretary (if so
17 prescribed), the Secretary may, by order, require, as the
18 Secretary deems necessary, such person to immediately
19 cease distribution of such article.

20 “(b) **HEARING.**—The Secretary shall provide the re-
21 sponsible person who is subject to an order under para-
22 graph (a) with an opportunity for an informal hearing,
23 to be held not later than 10 days after the date of issuance
24 of the order, on whether adequate evidence exists to justify

1 the order, and what actions are required by such amended
2 order pursuant to subsection (c).

3 “(c) ORDER RESOLUTION.—After an order is issued
4 according to the process under subsections (a) and (b),
5 the Secretary shall, except as provided in subsection (d)—

6 “(1) vacate the order, if the Secretary deter-
7 mines that inadequate grounds exist to support the
8 actions required by the order;

9 “(2) continue the order ceasing distribution of
10 the cosmetic until a date specified in such order; or

11 “(3) amend the order to require a recall of the
12 cosmetic, including any requirements to notify ap-
13 propriate persons, a timetable for the recall to occur,
14 and a schedule for updates to be provided to the
15 Secretary regarding such recall.

16 “(d) ACTION FOLLOWING ORDER.—Any person who
17 is subject to an order pursuant to paragraph (2) or (3)
18 of subsection (c) shall immediately cease distribution of
19 or recall, as applicable, the cosmetic and provide notifica-
20 tion as required by such order.

21 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
22 retary determines necessary, the Secretary may require
23 the person subject to an order pursuant to subsection (a)
24 or an amended order pursuant to paragraph (2) or (3)
25 of subsection (c) to provide either a notice of a recall order

1 for, or an order to cease distribution of, such cosmetic,
2 as applicable, under this section to appropriate persons,
3 including persons who manufacture, distribute, import, or
4 offer for sale such product that is the subject of an order
5 and to the public.

6 “(f) PUBLIC NOTIFICATION.—In conducting a recall
7 under this section, the Secretary shall—

8 “(1) ensure that a press release is published re-
9 garding the recall, and that alerts and public notices
10 are issued, as appropriate, in order to provide notifi-
11 cation—

12 “(A) of the recall to consumers and retail-
13 ers to whom such cosmetic was, or may have
14 been, distributed; and

15 “(B) that includes, at a minimum—

16 “(i) the name of the cosmetic subject
17 to the recall;

18 “(ii) a description of the risk associ-
19 ated with such article; and

20 “(iii) to the extent practicable, infor-
21 mation for consumers about similar cos-
22 metics that are not affected by the recall;
23 and

24 “(2) ensure publication, as appropriate, on the
25 website of the Food and Drug Administration of an

1 image of the cosmetic that is the subject of the press
2 release described in paragraph (1), if available.

3 “(g) NO DELEGATION.—The authority conferred by
4 this section to order a recall or vacate a recall order shall
5 not be delegated to any officer or employee other than the
6 Commissioner.

7 “(h) EFFECT.—Nothing in this section shall affect
8 the authority of the Secretary to request or participate
9 in a voluntary recall, or to issue an order to cease distribu-
10 tion or to recall under any other provision of this chapter.

11 **“SEC. 612. SMALL BUSINESSES.**

12 “(a) IN GENERAL.—Responsible persons, and owners
13 and operators of facilities, whose average gross annual
14 sales in the United States of cosmetic products for the
15 previous 3-year period is less than \$1,000,000, adjusted
16 for inflation, and who do not engage in the manufacturing
17 or processing of the cosmetic products described in sub-
18 section (b), shall be considered small businesses and not
19 subject to the requirements of section 606 or 607.

20 “(b) REQUIREMENTS APPLICABLE TO ALL MANU-
21 FACTURERS AND PROCESSORS OF COSMETICS.—The ex-
22 emptions under subsection (a) shall not apply to any re-
23 sponsible person or facility engaged in the manufacturing
24 or processing of any of the following products:

1 “(1) Cosmetic products that regularly come into
2 contact with mucus membrane of the eye under con-
3 ditions of use that are customary or usual.

4 “(2) Cosmetic products that are injected.

5 “(3) Cosmetic products that are intended for
6 internal use.

7 “(4) Cosmetic products that are intended to
8 alter appearance for more than 24 hours under con-
9 ditions of use that are customary or usual and re-
10 moval by the consumer is not part of such conditions
11 of use that are customary or usual.

12 **“SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FA-**
13 **CILITIES.**

14 “(a) IN GENERAL.—Notwithstanding any other pro-
15 vision of law, except as provided in subsection (b), a cos-
16 metic product or facility that is also subject to the require-
17 ments of chapter V shall be exempt from the requirements
18 of sections 605, 606, 607, 608, 609(a), 610, and 611.

19 “(b) EXCEPTION.—A facility described in subsection
20 (a) that also manufactures or processes cosmetic products
21 that are not subject to the requirements of chapter V shall
22 not be exempt from the requirements of sections 605, 606,
23 607, 608, 609(a), 610, and 611, with respect to such cos-
24 metic products.

1 **“SEC. 614. PREEMPTION.**

2 “(a) IN GENERAL.—No State or political subdivision
3 of a State may establish or continue in effect any law,
4 regulation, order, or other requirement for cosmetics that
5 is different from or in addition to, or otherwise not iden-
6 tical with, any requirement applicable under this chapter
7 with respect to registration and product listing, good man-
8 ufacturing practice, recordkeeping, recalls, adverse event
9 reporting, or safety substantiation.

10 “(b) LIMITATION.—Nothing in the amendments to
11 this Act made by the Modernization of Cosmetics Regula-
12 tion Act of 2022 shall be construed to preempt any State
13 statute, public initiative, referendum, regulation, or other
14 State action, except as expressly provided in subsection
15 (a). Notwithstanding subsection (a), nothing in this sec-
16 tion shall be construed to prevent any State from prohib-
17 iting the use or limiting the amount of an ingredient in
18 a cosmetic product.

19 “(c) SAVINGS.—Nothing in the amendments to this
20 Act made by the Modernization of Cosmetics Regulation
21 Act of 2022, nor any standard, rule, requirement, regula-
22 tion, or adverse event report shall be construed to modify,
23 preempt, or displace any action for damages or the liabil-
24 ity of any person under the law of any State, whether stat-
25 utory or based in common law.

1 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to amend, expand, or limit the pro-
3 visions under section 752.”.

4 **SEC. 803. ENFORCEMENT AND CONFORMING AMEND-**
5 **MENTS.**

6 (a) IN GENERAL.—

7 (1) PROHIBITED ACTS.—Section 301 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 331) is amended—

10 (A) by adding at the end the following:

11 “(fff) The failure to register or submit listing infor-
12 mation in accordance with section 607.

13 “(ggg) The refusal or failure to follow an order under
14 section 611.”; and

15 (B) in paragraph (d), by striking “or 564”
16 and inserting “, 564, or 607”.

17 (2) ADULTERATED PRODUCTS.—Section 601 of
18 the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 361) is amended by adding at the end the
20 following:

21 “(f) If it has been manufactured or processed under
22 conditions that do not meet current good manufacturing
23 practice regulations, as prescribed by the Food and Drug
24 Administration in accordance with section 606.

1 “(g) If it is a cosmetic product, and the cosmetic
2 product, including each ingredient in the cosmetic product,
3 does not have adequate substantiation for safety, as de-
4 fined in section 608(c).”.

5 (3) MISBRANDED COSMETICS.—Section 602(b)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 362(b)) is amended—

8 (A) by striking “and (2)” and inserting
9 “(2)”; and

10 (B) by inserting after “numerical count”
11 the following: “; and (3) the information re-
12 quired under section 609”.

13 (4) ADVERSE EVENT REPORTING.—The Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
15 seq.) is amended—

16 (A) in section 301(e) (21 U.S.C. 331(e))—

17 (i) by striking “564, 703” and insert-
18 ing “564, 605, 703”; and

19 (ii) by striking “564, 760” and insert-
20 ing “564, 605, 611, 760”;

21 (B) in section 301(ii) (21 U.S.C.
22 331(ii))—

23 (i) by striking “760 or 761) or” and
24 inserting “604, 760, or 761) or”; and

1 (ii) by inserting “or required under
2 section 605(a)” after “report (as defined
3 under section 760 or 761”;

4 (C) in section 801(a) (21 U.S.C. 381(a))—

5 (i) by striking “under section 760 or
6 761” and inserting “under section 605,
7 760, or 761”;

8 (ii) by striking “defined in such sec-
9 tion 760 or 761” and inserting “defined in
10 section 604, 760, or 761”;

11 (iii) by striking “of such section 760
12 or 761” and inserting “of such section
13 605, 760, or 761”; and

14 (iv) by striking “described in such
15 section 760 or 761” and inserting “de-
16 scribed in such section 605, 760, or 761”;
17 and

18 (D) in section 801(b) (21 U.S.C.
19 381(b))—

20 (i) by striking “requirements of sec-
21 tions 760 or 761,” and inserting “require-
22 ments of section 605, 760, or 761”;

23 (ii) by striking “as defined in section
24 760 or 761” and inserting “as defined in
25 section 604, 760, or 761”; and

1 (iii) by striking “with section 760 or
2 761” and inserting “with section 605, 760,
3 or 761”.

4 (b) EFFECTIVE DATE.—The amendments made by
5 subsection (a) shall take effect on the date that is 1 year
6 after the date of enactment of this Act.

7 **SEC. 804. RECORDS INSPECTION.**

8 Section 704(a)(1) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by insert-
10 ing after the second sentence the following: “In the case
11 of a facility (as defined in section 604) that manufactures
12 or processes cosmetic products, the inspection shall extend
13 to all records and other information described in section
14 610, when the standard for records inspection under such
15 section applies.”.

16 **SEC. 805. TALC-CONTAINING COSMETICS.**

17 The Secretary of Health and Human Services—

18 (1) not later than one year after the date of en-
19 actment of this Act, shall promulgate proposed regu-
20 lations to establish standardized testing methods for
21 detecting and identifying asbestos in talc-containing
22 cosmetic products; and

23 (2) not later than 180 days after the date on
24 which the public comment period on the proposed
25 regulations closes, shall issue such final regulations.

1 **SEC. 806. FUNDING.**

2 To carry out the amendments made by sections 802,
3 803, 804, and 805, there is authorized to be appropriated
4 **[\$_____]** for each of the fiscal years 2023 through 2029
5 and such sums as may be necessary for each of the subse-
6 quent fiscal years, to remain available until expended.

7 **Subtitle B—Dietary Supplements**

8 **SEC. 811. REGULATION OF DIETARY SUPPLEMENTS.**

9 (a) IN GENERAL.—Chapter IV of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
11 ed by adding after section 403C of such Act (21 U.S.C.
12 343–3) the following:

13 **“SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIRE-**
14 **MENT.**

15 “(a) IN GENERAL.—Beginning on the date specified
16 in subsection (b)(4), each dietary supplement shall be list-
17 ed with the Secretary in accordance with this section.
18 Each such listing shall include, with respect to the dietary
19 supplement, the information specified in subsection (b)(1).

20 “(b) REQUIREMENTS.—

21 “(1) IN GENERAL.—The manufacturer, packer,
22 or distributor of a dietary supplement whose name
23 (pursuant to section 403(e)(1)) appears on the label
24 of a dietary supplement marketed in the United
25 States (referred to in this section as the ‘responsible
26 person’), or if the responsible person is a foreign en-

1 tity, the United States agent of such person, shall
2 submit to the Secretary in accordance with this sec-
3 tion the following information for a dietary supple-
4 ment that is marketed:

5 “(A) Any name of the dietary supplement
6 and the statement of identity, including brand
7 name and specified flavors, if applicable.

8 “(B) The name and address of the respon-
9 sible person and the name and email address of
10 the owner, operator, or agent in charge of the
11 responsible person.

12 “(C) The name, domestic address, and
13 email address for the United States agent, if
14 the responsible person is a foreign entity.

15 “(D) The business name and mailing ad-
16 dress of all locations at which the responsible
17 person manufactures, packages, labels, or holds
18 the dietary supplement.

19 “(E) A list of all ingredients in each such
20 dietary supplement required under sections
21 101.4 and 101.36, title 21, Code of Federal
22 Regulations (or any successor regulations) to
23 appear on the label of a dietary supplement, in-
24 cluding—

1 “(i) where applicable, ingredients in a
2 proprietary blend as described in section
3 101.36(e) of title 21, Code of Federal Reg-
4 ulations (or any successor regulations);

5 “(ii) the amount per serving of each
6 listed dietary ingredient;

7 “(iii) if required by section 101.36 of
8 title 21, Code of Federal Regulations (or
9 any successor regulations), the percent of
10 the daily value of each listed ingredient;
11 and

12 “(iv) the amount per serving of die-
13 tary ingredients within a proprietary blend.

14 “(F) The number of servings per container
15 for each container size.

16 “(G) The directions for use.

17 “(H) Warnings, notice, and safe handling
18 statements, as required by section 101.17 of
19 title 21, Code of Federal Regulations (or any
20 successor regulations).

21 “(I) Allergen statements for major food al-
22 lergens (pursuant to sections 403(w) and
23 403(x)).

24 “(J) The form of the dietary supplement
25 (such as tablets, capsules).

1 commerce on or before January 1, 2024, a
2 listing for each such dietary supplement in-
3 troduced or delivered for introduction into
4 interstate commerce shall be submitted by
5 the responsible person to the Secretary
6 under this subsection not later than 18
7 months after the date of enactment of the
8 **[*short title*]**.

9 “(ii) NEW DIETARY SUPPLEMENTS.—
10 In the case of a dietary supplement that is
11 not being offered in interstate commerce
12 on or before January 1, 2024, a listing for
13 each such dietary supplement introduced
14 or delivered for introduction into interstate
15 commerce that has not been included in
16 any listing previously submitted by the re-
17 sponsible person to the Secretary under
18 this subsection shall be submitted to the
19 Secretary at the time of introduction into
20 interstate commerce.

21 “(B) DISCONTINUED DIETARY SUPPLE-
22 MENTS.—The responsible person shall notify
23 the Secretary within one year of the date of dis-
24 continuance of a dietary supplement required to
25 be listed with the Secretary under paragraph

1 (1) for which the responsible person has discon-
2 tinued commercial marketing.

3 “(C) CHANGES TO EXISTING LISTINGS.—

4 The responsible person shall submit to the Sec-
5 retary a change or modification to listing infor-
6 mation submitted under paragraph (1) included
7 on the label for a dietary supplement at the
8 time the dietary supplement with the change or
9 modification is introduced into interstate com-
10 merce.

11 “(5) ADDITIONAL INFORMATION.—The respon-
12 sible person shall provide upon request from the Sec-
13 retary, within 10 calendar days of such request, the
14 full business name and physical and mailing address
15 from which the responsible person receives a dietary
16 ingredient or combination of dietary ingredients that
17 the responsible person uses in the manufacture of
18 the dietary supplement or, if applicable, from which
19 the responsible person receives the dietary supple-
20 ment.

21 “(c) PRODUCT LISTING NUMBER AND DIETARY SUP-
22 PLEMENT ELECTRONIC DATABASE.—

23 “(1) DIETARY SUPPLEMENT PRODUCT LISTING
24 NUMBER.—The Secretary shall provide each dietary
25 supplement listed in accordance with subsection

1 (b)(1) a dietary supplement product listing number,
2 which may apply to multiple dietary supplements
3 with identical formulations, or formulations that dif-
4 fer only with respect to color, additives, or
5 flavorings, including dietary supplements offered in
6 a single package size or in multiple package sizes.
7 The Secretary shall provide a process for a respon-
8 sible person to reserve dietary supplement listing
9 numbers in advance of listing under subsection
10 (b)(1).

11 “(2) ELECTRONIC DATABASE.—Not later than
12 2 years after the date of enactment of the [short
13 title], the Secretary shall establish and maintain an
14 electronic database that is publicly available and
15 contains information submitted under subsection
16 (b)(1) (except for the information submitted under
17 subparagraphs (D) and (E)(iv) of such subsection).
18 The Secretary shall make such information main-
19 tained in the electronic database publicly searchable,
20 including by dietary supplement product listing
21 number, and by any field of information or combina-
22 tion of fields of information provided under sub-
23 section (b)(1).

24 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed—

1 “(1) to limit the authority of the Secretary to
2 inspect or copy records or to require the establish-
3 ment and maintenance of records under any other
4 provision of this Act; or

5 “(2) to authorize the disclosure of confidential
6 commercial information, as prohibited under section
7 301(j) of this Act or section 1905 of title 18, United
8 States Code, including information provided to the
9 Secretary under subsection (b)(1)(D) or
10 (b)(1)(E)(iv).

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
12 is authorized to be appropriated for fiscal year **[xxx]** and
13 each subsequent fiscal year, **[\$xxx]** for purposes of con-
14 ducting the activities under this section and hiring per-
15 sonnel required to carry out this section.”.

16 (b) GUIDANCE.—Not later than 18 months after the
17 date of enactment of this Act, the Secretary of Health and
18 Human Services shall publish final guidance related to the
19 draft guidance titled, “New Dietary Ingredient Notifica-
20 tions and Related Issues”, issued in October 2016, con-
21 sistent with section 403D of the Federal Food, Drug, and
22 Cosmetic Act, as added by subsection (a).

23 (c) INSPECTIONS FOR CERTAIN DIETARY SUPPLE-
24 MENTS.—The Secretary of Health and Human Services
25 shall direct resources to inspections of facilities, suppliers,

1 and dietary supplement types that present a high risk to
2 public health (as identified by the Secretary).

3 (d) MISBRANDING.—Section 403 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
5 ed by adding at the end the following:

6 “(z) If it is a dietary supplement for which a respon-
7 sible person is required under section 403D to file a
8 listing[■], file a change to an existing listing, or provide ad-
9 ditional information to the Secretary[■] and such person
10 has not made a listing[■], filed a change, or provided the
11 additional information[■] in compliance with section 403D
12 with respect to such dietary supplement.”.

13 [■](e) NEW PROHIBITED ACT.—Section 301 of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331),
15 as amended by section 803(a), is further amended by add-
16 ing at the end the following: [■]

17 [■]“(hhh) The introduction or delivery for introduction
18 into interstate commerce of any product marketed as a
19 dietary supplement that does not meet the definition of
20 a dietary supplement under section 201(ff).” [■]

21 [■]“(iii) The introduction or delivery for introduction
22 into interstate commerce of a dietary supplement that has
23 been prepared, packed, or held using the assistance of, or
24 at the direction of, a person debarred under section
25 306.” [■]

1 **Subtitle C—In Vitro Clinical Tests**

2 **SEC. 821. SHORT TITLE; TABLE OF CONTENTS.**

3 (a) SHORT TITLE.—This subtitle may be cited as the
 4 “Verifying Accurate Leading-edge IVCT Development Act
 5 of 2022” or the “VALID Act of 2022”.

6 (b) TABLE OF CONTENTS.—The table of contents of
 7 this subtitle is as follows:

SUBCHAPTER C—IN VITRO CLINICAL TESTS

- Sec. 821. Short title; table of contents.
- Sec. 822. Definitions.
- Sec. 823. Regulation of in vitro clinical tests.

“SUBCHAPTER J—IN VITRO CLINICAL TESTS

“SUBCHAPTER J. In Vitro Clinical Tests

- “Sec. 587. Definitions.
- “Sec. 587A. Regulation of in vitro clinical tests.
- “Sec. 587B. Premarket review.
- “Sec. 587C. Exemptions.
- “Sec. 587D. Technology certification.
- “Sec. 587E. Mitigating measures.
- “Sec. 587F. Regulatory pathway designation.
- “Sec. 587G. Grandfathered in vitro clinical tests.
- “Sec. 587H. Advisory committees.
- “Sec. 587I. Breakthrough in vitro clinical tests.
- “Sec. 587J. Registration and listing.
- “Sec. 587K. Test design and quality requirements.
- “Sec. 587L. Labeling requirements.
- “Sec. 587M. Adverse event reporting.
- “Sec. 587N. Corrections and removals.
- “Sec. 587O. Restricted in vitro clinical tests.
- “Sec. 587P. Appeals.
- “Sec. 587Q. Accredited persons.
- “Sec. 587R. Recognized standards.
- “Sec. 587S. Investigational use.
- “Sec. 587T. Collaborative communities for in vitro clinical tests.
- “Sec. 587U. Comprehensive test information system.
- “Sec. 587V. Preemption.
- “Sec. 587W. Adulteration.
- “Sec. 587X. Misbranding.
- “Sec. 587Y. Postmarket surveillance.
- “Sec. 587Z. Electronic format for submissions.
- “Sec. 587AA. Postmarket remedies.
- “Sec. 587BB. Applicability.
- “Sec. 587CC. Judicial review.
- Sec. 824. Enforcement and other provisions.

Sec. 825. Transition.
Sec. 826. Emergency use authorization.
Sec. 827. Antimicrobial susceptibility tests.
Sec. 828. Combination products.
Sec. 829. Resources.

1 **SEC. 822. DEFINITIONS.**

2 (a) IN GENERAL.—Section 201 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

4 (1) by adding at the end the following:

5 “(ss)(1) The term ‘in vitro clinical test’ means an ar-
6 ticle specified in subparagraph (2) that is intended by its
7 developer (as defined in section 587) to be used in the
8 collection, preparation, analysis, or in vitro clinical exam-
9 ination of specimens taken or derived from the human
10 body for the purpose of—

11 “(A) identifying or diagnosing a disease or con-
12 dition;

13 “(B) providing information for diagnosing,
14 screening, measuring, detecting, predicting,
15 prognosing, analyzing, or monitoring a disease or
16 condition, including by making a determination of
17 an individual’s state of health; or

18 “(C) selecting, monitoring, or informing ther-
19 apy or treatment for a disease or condition.

20 “(2) An article specified in this subparagraph is—

21 “(A) a test kit;

22 “(B) a test system;

23 “(C) a test protocol or laboratory test protocol;

1 “(D) an instrument (as defined in section
2 587(10));

3 “(E) a specimen receptacle (as defined in sec-
4 tion 587(15));

5 “(F) software, excluding software that is ex-
6 cluded by section 520(o) from the definition of a de-
7 vice under section 201(h); and

8 “(G) subject to subparagraph (3), a component
9 or part of a test, a test protocol, an instrument, an
10 article, or software described in any of clauses (A)
11 through (D) of such subparagraph, whether alone or
12 in combination, including reagents, calibrators, and
13 controls.

14 “(3) Notwithstanding subparagraph (2)(E), an arti-
15 cle intended to be used as a component or part of an in
16 vitro clinical test described in subparagraph (1) is ex-
17 cluded from the definition in subparagraph (1) if the arti-
18 cle consists of any of the following:

19 “(A) Blood, blood components, or human cells
20 or tissues, from the time of acquisition, donation, or
21 recovery of such article, including determination of
22 donor eligibility, as applicable, until such time as the
23 article is released as a component or part of an in
24 vitro clinical test by the establishment that collected
25 such article.

1 “(B) An article used for invasive sampling, a
2 needle, or a lancet, except to the extent such article,
3 needle, or lancet is an integral component of an arti-
4 cle for holding, storing, or transporting a specimen.

5 “(C) General purpose laboratory equipment, in-
6 cluding certain pre-analytical equipment, as deter-
7 mined by the Secretary.

8 “(D) An article used solely for personal protec-
9 tion during the administering, conducting, or other-
10 wise performing of test activities.”;

11 (2) by adding at the end of section 201(g) the
12 following:

13 “(3) The term ‘drug’ does not include an in vitro clin-
14 ical test.”; and

15 (3) in section 201(h)(1), by striking “section
16 520(o)” and inserting “section 520(o) or an in vitro
17 clinical test”.

18 (b) EXCLUSION FROM DEFINITION OF BIOLOGICAL
19 PRODUCT.—Section 351(i)(1) of the Public Health Serv-
20 ice Act (42 U.S.C. 262(i)(1)) is amended—

21 (1) by striking “(1) The term ‘biological prod-
22 uct’ means” and inserting “(1)(A) The term ‘biologi-
23 cal product’ means”; and

24 (2) by adding at the end the following:

1 “(B) The term ‘biological product’ does not in-
2 clude an in vitro clinical test as defined in section
3 201(ss) of the Federal Food, Drug, and Cosmetic
4 Act.”.

5 (c) IN VITRO CLINICAL TEST DEFINITION.—In this
6 Act, the term “in vitro clinical test” has the meaning given
7 such term in section 201(ss) of the Federal Food, Drug,
8 and Cosmetic Act, as added by subsection (a).

9 **SEC. 823. REGULATION OF IN VITRO CLINICAL TESTS.**

10 The Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 301 et seq.) is amended—

12 (1) by amending the heading of chapter V to
13 read as follows: “**DRUGS, DEVICES, AND IN**
14 **VITRO CLINICAL TESTS**”; and

15 (2) by adding at the end of chapter V the fol-
16 lowing:

17 **“Subchapter J—In Vitro Clinical Tests**

18 **“SEC. 587. DEFINITIONS.**

19 “In this subchapter:

20 “(1) ANALYTICAL VALIDITY.—

21 “(A) The term ‘analytical validity’ means,
22 with respect to an in vitro clinical test, the abil-
23 ity of the in vitro clinical test, to identify, meas-
24 ure, detect, calculate, or analyze (or assist in
25 such identification, measurement, detection, cal-

1 culation, or analysis of) one or more analytes,
2 biomarkers, substances, or other targets in-
3 tended to be identified, measured, detected, cal-
4 culated, or analyzed by the test.

5 “(2) APPLICABLE STANDARD.—The term ‘ap-
6 plicable standard’, with respect to an in vitro clinical
7 test, means a reasonable assurance of analytical and
8 clinical validity **【for its intended use】**, and a reason-
9 able assurance of safety for individuals who come
10 into contact with such in vitro clinical test, except
11 that such term, with respect to specimen receptacles,
12 test instruments, means a reasonable assurance of
13 analytical validity, and, where applicable, safety for
14 individuals who come into contact with such speci-
15 men receptacle.

16 “(3) CLINICAL USE.—The term ‘clinical use’
17 means the operation, application, or functioning of
18 an in vitro clinical test for the purpose for which it
19 is intended as described in section 201(ss)(1).

20 “(4) CLINICAL VALIDITY.—The term ‘clinical
21 validity’ means the ability of an in vitro clinical test
22 to achieve the purpose for which it is intended as de-
23 scribed in section 201(ss)(1).

24 “(5) COMPONENT OR PART.—The term ‘compo-
25 nent or part’ means a substance, piece, part , raw

1 material, software, firmware, labeling, or assembly,
2 including reagents, that is intended by the developer
3 to be included as an aspect of, and is useful for per-
4 forming the intended use of, an in vitro clinical test
5 described in section 201(ss) **[(1)]**.

6 “(6) DEVELOP.—The term ‘develop’, with re-
7 spect to an in vitro clinical test, means—

8 “(A) designing, validating, producing,
9 manufacturing, remanufacturing, labeling, ad-
10 vertising, propagating, or assembling an in vitro
11 clinical test;

12 “(B) modifying an in vitro clinical test, in-
13 cluding modifying the intended use of the in
14 vitro clinical test, or modifying an article to be
15 in an in vitro clinical test;

16 “(C) adopting, using, or disseminating for
17 use as an in vitro clinical test an article not
18 previously intended for clinical use;

19 “(D) establishing a test system as de-
20 scribed in a test protocol developed by another
21 entity unless such test protocol is listed as an
22 in vitro clinical test in the comprehensive test
23 information system established under section
24 587U by that other entity; or

1 “(E) adopting, using, or disseminating for
2 use as an in vitro clinical test an article not
3 previously intended for clinical use.

4 “(7) DEVELOPER.—The term ‘developer’ means
5 a person who engages in development as described in
6 paragraph (6), except the term does not include a
7 laboratory that—

8 “(A) is certified by the Secretary under
9 section 353 of the Public Health Service Act;
10 and

11 “(B) assembles for use solely within that
12 laboratory, without otherwise developing, an in
13 vitro clinical test appropriately listed in the
14 comprehensive test information system estab-
15 lished under section 587U by a different per-
16 son.

17 “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-
18 kind’, with respect to an in vitro clinical test, means
19 that such test has any novel combination of the ele-
20 ments specified in paragraph (10) [and is based on
21 technology that differs] from in vitro clinical tests
22 that already are legally available in the United
23 States.

24 “(9) HIGH-RISK.—The term ‘high-risk’, with
25 respect to an in vitro clinical test or category of in

1 vitro clinical tests, means that an undetected inac-
2 curate result from such test, or such category of
3 tests, when used as intended—

4 “(A)(i) has the substantial likelihood to re-
5 sult in serious or irreversible harm or death to
6 a patient or patients, or would otherwise cause
7 serious harm to the public health; or

8 “(ii) is reasonably likely to result in the
9 absence, significant delay, or discontinuation of
10 life-supporting or life-sustaining medical treat-
11 ment; and

12 “(B) sufficient mitigating measures are
13 not able to be established and applied to pre-
14 vent, mitigate, or detect the inaccurate result,
15 or otherwise mitigate the risk resulting from an
16 undetected inaccurate result described in sub-
17 paragraph (A).

18 “(10) INDICATIONS FOR USE.—The term ‘indi-
19 cations for use’ means one or more in vitro clinical
20 tests that have all of the following notification ele-
21 ments in common:

22 “(A) Substance or substances measured by
23 the in vitro clinical test, such as an analyte,
24 protein, or pathogen.

25 “(B) Test method.

1 “(C) Test purpose or purposes, as de-
2 scribed in section 201(ss)(1).

3 “(D) Diseases or conditions for which the
4 in vitro clinical test is intended for use, includ-
5 ing intended patient populations.

6 “(E) Context of use, such as in a clinical
7 laboratory, in a health care facility, prescription
8 home use, over-the-counter use, or direct-to-
9 consumer testing.

10 “(11) INSTRUMENT.—The term ‘instrument’
11 means an in vitro clinical test that is hardware in-
12 tended by the hardware developer to be used with
13 one or more other in vitro clinical tests to generate
14 a clinical test result, including software used to ef-
15 fectuate the functionality of the hardware.

16 “(12) INSTRUMENT FAMILY.—The term ‘instru-
17 ment family’ means more than one instrument devel-
18 oped by the same developer for which the developer
19 demonstrates and documents, with respect to all
20 such instruments, that all—

21 “(A) have the same basic architecture, de-
22 sign, and performance characteristics;

23 “(B) have the same intended use and capa-
24 bilities;

1 “(C) share the same measurement prin-
2 ciples, detection methods, and reaction condi-
3 tions, as applicable; and

4 “(D) produce the same or similar analyt-
5 ical results from samples of the same specimen
6 type or types.

7 “(13) LABORATORY OPERATIONS.—The term
8 ‘laboratory operations’—

9 “(A) means the conduct of a laboratory ex-
10 amination or other laboratory procedure on ma-
11 terials derived from the human body, including
12 the conduct of an in vitro clinical test and asso-
13 ciated activities within or under the oversight of
14 a laboratory and not related to the design of an
15 in vitro clinical test; and

16 “(B) includes—

17 “(i) performing pre-analytical and
18 post-analytical processes for an in vitro
19 clinical test;

20 “(ii) standard operating procedures
21 and the conduct thereof; and

22 “(iii) preparing reagents or other test
23 materials that do not meet the definition of
24 an in vitro clinical test for clinical use
25 under section 201(ss).

1 “(14) LOW-RISK.—The term ‘low-risk’, with re-
2 spect to an in vitro clinical test or category of in
3 vitro clinical tests, means that an undetected inac-
4 curate result from such in vitro clinical test, or such
5 category of in vitro clinical tests, when used as in-
6 tended—

7 “(A) would cause only minimal or imme-
8 diately reversible harm, and would lead to only
9 a remote risk of adverse patient impact or ad-
10 verse public health impact; or

11 “(B) sufficient mitigating measures are
12 able to be established and applied such that the
13 in vitro clinical test meets the standard de-
14 scribed in subparagraph (A).

15 “(15) MITIGATING MEASURES.—The term
16 ‘mitigating measures’—

17 “(A) means controls, standards, and other
18 requirements that the Secretary determines,
19 based on evidence, are necessary—

20 “(i) for an in vitro clinical test, or a
21 category of in vitro clinical tests, to meet
22 the applicable standard; or

23 “(ii) to mitigate the risk of harm en-
24 suing from an unidentified inaccurate re-
25 sult or misinterpretation of a result; and

1 “(B) may include, as required by the Sec-
2 retary, as appropriate, applicable requirements
3 regarding labeling, conformance to performance
4 standards and consensus standards, perform-
5 ance testing, submission of clinical data, adver-
6 tising, website posting of information, clinical
7 studies, postmarket surveillance, user com-
8 prehension studies, training, and confirmatory
9 laboratory, clinical findings, or testing.

10 “(16) MODERATE-RISK.—The term ‘moderate-
11 risk’, with respect to an in vitro clinical test or cat-
12 egory of in vitro clinical tests, means that, when
13 used as intended, such test or category of tests—

14 “(A) meets the criteria specified in para-
15 graph (9) for classification as high-risk, but one
16 or more mitigating measures are able to be es-
17 tablished and applied to sufficiently prevent or
18 detect an inaccurate result or otherwise miti-
19 gate such risk; or

20 “(B)(i) an inaccurate result for the in-
21 tended use of the test would cause only non-life-
22 threatening injury, injury that is medically re-
23 versible, or significant delay in necessary treat-
24 ment if such inaccurate result were undetected
25 when used as intended;

1 “(ii) no mitigating measures are able to be
2 established and applied to prevent or detect
3 such inaccurate result or otherwise mitigate the
4 risk of such inaccurate result; and

5 “(iii) there is a reasonable risk of adverse
6 patient impact or adverse public health impact
7 caused by an undetected inaccurate result.

8 “(17) SPECIMEN RECEPTACLE.—The term
9 ‘specimen receptacle’ means an in vitro clinical test
10 intended for taking, collecting, holding, storing, or
11 transporting of specimens derived from the human
12 body or for in vitro examination for purposes de-
13 scribed in subparagraph (A) or (B) of section
14 201(ss)(1).

15 “(18) TECHNOLOGY.—The term ‘technology’—
16 “(A) means a set of control mechanisms,
17 energy sources, or operating principles—

18 “(i) that do not differ significantly
19 among multiple in vitro clinical tests; and

20 “(ii) for which design and develop-
21 ment (including analytical and clinical vali-
22 dation, as applicable) of the tests would be
23 addressed in a similar manner or through
24 similar procedures; and

1 “(B) may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture, next generation sequencing, nephelometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, signal-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

13 “(19) TEST.—The term ‘test’, unless otherwise provided, means an in vitro clinical test.

15 “(20) VALID SCIENTIFIC EVIDENCE.—The term ‘valid scientific evidence’—

17 “(A) means, with respect to an in vitro clinical test, evidence **【**that the Secretary determines**】**—

20 “(i) has been generated and evaluated by persons qualified by training or experience to do so, using procedures generally accepted by other persons so qualified; and

24 “(ii) forms an appropriate basis for concluding by qualified experts whether the

1 applicable standard has been met by the in
2 vitro clinical test for its intended use; and
3 “(B) may include evidence described in
4 subparagraph (A) consisting of—
5 “(i) peer-reviewed literature;
6 “(ii) clinical guidelines;
7 “(iii) reports of significant human ex-
8 perience with an in vitro clinical test;
9 “(iv) bench studies;
10 “(v) case studies or histories;
11 “(vi) clinical data;
12 “(vii) consensus standards;
13 “(viii) reference standards;
14 “(ix) data registries;
15 “(x) postmarket data;
16 “(xi) real world data;
17 “(xii) clinical trials; and
18 “(xiii) data collected in countries
19 other than the United States if such data
20 are demonstrated to be appropriate for the
21 purpose of making a regulatory determina-
22 tion under this subchapter.

1 **“SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.**

2 “(a) IN GENERAL.—No person shall introduce or de-
3 liver for introduction into interstate commerce any in vitro
4 clinical test, unless—

5 “(1) an approval of an application filed pursu-
6 ant to subsection (a) or (b) of section 587B is effec-
7 tive with respect to such in vitro clinical test; or

8 “(2) a technology certification order is in effect
9 under section 587D; or

10 “(3) the test is exempt under [sections 587C or
11 587G] from the requirements of section 587B.

12 “(b) TRANSFER OR SALE OF IN VITRO CLINICAL
13 TESTS.—

14 “(1) TRANSFER AND ASSUMPTION OF REGU-
15 LATORY OBLIGATIONS.—If ownership of an in vitro
16 clinical test is sold or transferred in such manner
17 that the developer transfers the regulatory submis-
18 sions and obligations applicable under this sub-
19 chapter with respect to the test, the transferee or
20 purchaser becomes the developer of the test and
21 shall have all regulatory obligations applicable to
22 such a test under this subchapter. The transferee or
23 purchaser shall update the registration and listing
24 information under section 587J for the in vitro clin-
25 ical test.

1 “(2) TRANSFER OR SALE OF PREMARKET AP-
2 PROVAL.—

3 “(A) NOTICE REQUIRED.—If a developer
4 of an in vitro clinical test transfers or sells the
5 approval of the in vitro clinical test, the trans-
6 feror or seller shall—

7 “(i) submit a notice of the transfer or
8 sale to the Secretary and update the reg-
9 istration and listing information under sec-
10 tion 587J for the in vitro clinical test; and

11 “(ii) submit a supplement to an appli-
12 cation if required under section 587B(h).

13 “(B) EFFECTIVE DATE OF APPROVAL
14 TRANSFER.—A transfer or sale described in
15 subparagraph (A) shall become effective upon
16 completion of a transfer or sale described in
17 paragraph (1) or the approval of a supplement
18 to an application under section 587B(h) if re-
19 quired, whichever is later. The transferee or
20 purchaser shall update the registration and list-
21 ing information under section 587J for the in
22 vitro clinical test within 15 calendar days of the
23 effective date of the transfer or sale.

24 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-
25 TIFICATION.—

1 “(A) REQUIREMENTS FOR TRANSFER OR
2 SALE OF TECHNOLOGY CERTIFICATION.—An
3 unexpired technology certification can be trans-
4 ferred or sold if the transferee or purchaser—

5 “(i) is an eligible person under section
6 587D(a)(2); and

7 “(ii) maintains, upon such transfer or
8 sale, test design and quality requirements,
9 processes and procedures under the scope
10 of technology certification, and scope of the
11 technology certification identified in the
12 applicable technology certification order.

13 “(B) NOTICE REQUIRED.—If a developer
14 of an in vitro clinical test transfers or sells a
15 technology certification order that has not ex-
16 pired, the transferor or seller shall submit a no-
17 tice of the transfer or sale to the Secretary and
18 shall update the registration and listing infor-
19 mation under section 587J for all in vitro clin-
20 ical tests covered by the technology certifi-
21 cation.

22 “(C) EFFECTIVE DATE OF TECHNOLOGY
23 CERTIFICATION TRANSFER.—The transfer of a
24 technology certification shall become effective
25 upon completion of a transfer or sale described

1 in subparagraph (A). The transferee or pur-
2 chaser shall update the registration and listing
3 information under section 587J for the in vitro
4 clinical test within 30 calendar days of the ef-
5 fective date of the technology certification
6 transfer.

7 “(D) NEW TECHNOLOGY CERTIFICATION
8 REQUIRED.—If the requirements of subpara-
9 graph (A)(ii) are not met, the technology cer-
10 tification order may not be transferred and the
11 transferee or purchaser of an in vitro clinical
12 test is required to submit an application for
13 technology certification and obtain a technology
14 certification order prior to offering the test for
15 clinical use.

16 “(c) REGULATIONS.—The Secretary may issue regu-
17 lations to implement this subchapter.

18 **“SEC. 587B. PREMARKET REVIEW.**

19 “(a) APPLICATION.—

20 “(1) FILING.—Any developer may file with the
21 Secretary an application for premarket approval of
22 an in vitro clinical test under this subsection.

23 “(2) TRANSPARENCY AND PREDICTABILITY.—If
24 a developer files a premarket application under this
25 section and provides any additional documentation

1 required under section 587D, the in vitro clinical
2 test that is the subject of the premarket application
3 may be utilized as the representative in vitro clinical
4 test reviewed by the Secretary to support a tech-
5 nology certification order under section 587D.

6 “(3) APPLICATION CONTENT.—An application
7 submitted under paragraph (1) shall include the fol-
8 lowing, in such format as the Secretary specifies:

9 “(A) General information regarding the in
10 vitro clinical test, including—

11 “(i) the name and address of the ap-
12 plicant;

13 “(ii) the table of contents for the ap-
14 plication and the identification of the infor-
15 mation the applicant claims as trade secret
16 or confidential commercial or financial in-
17 formation;

18 “(iii) a description of the test’s design
19 and intended use, including the listing ele-
20 ments described in subparagraphs (F)
21 through (L) of section 587I(b)(2); and

22 “(iv) a description regarding test
23 function and performance characteristics.

1 “(B) A summary of the data and informa-
2 tion in the application for the in vitro clinical
3 test, including—

4 “(i) a brief description of the foreign
5 and domestic marketing history of the test,
6 if any, including a list of all countries in
7 which the test has been marketed and a
8 list of all countries in which the test has
9 been withdrawn from marketing for any
10 reason related to the ability of the in vitro
11 clinical test to meet the applicable stand-
12 ard, if known by the applicant;

13 “(ii) a description of benefit and risk
14 considerations related to the in vitro clin-
15 ical test, including a description of any ap-
16 plicable adverse effects of the test on
17 health and how such adverse effects have
18 been, or will be, mitigated;

19 “(iii) a risk assessment of the test;
20 and

21 “(iv) a description of how the data
22 and information in the application con-
23 stitute valid scientific evidence and support
24 a showing that the test meets the applica-
25 ble standard under section 587(2).

1 “(C) The signature of the developer filing
2 the premarket application or an authorized rep-
3 resentative.

4 “(D) A bibliography of applicable pub-
5 lished reports relied upon by the applicant and
6 a description of any studies conducted, includ-
7 ing any unpublished studies related to such
8 test, that are known or that should reasonably
9 be known to the applicant, and a description of
10 data and information relevant to the evaluation
11 of whether the test meets the applicable stand-
12 ard.

13 “(E) Applicable information regarding the
14 methods used in, and the facilities or controls
15 used for, the development of the test to dem-
16 onstrate compliance with the applicable quality
17 requirements under section 587K.

18 “(F) Information demonstrating compli-
19 ance with any relevant and applicable—

20 “(i) mitigating measures under sec-
21 tion 587E; and

22 “(ii) standards established or recog-
23 nized under section 514 prior to the date
24 of enactment of the VALID Act of 2022,
25 or, after applicable standards are estab-

1 lished or recognized under section 587Q,
2 with such standards.

3 “(G) Valid scientific evidence to support
4 that the test meets the applicable standard,
5 which shall include—

6 “(i) summary information for all sup-
7 porting validation studies performed, in-
8 cluding a description of the objective of the
9 study, a description of the experimental de-
10 sign of the study, a description of any limi-
11 tations of the study, a brief description of
12 how the data were collected and analyzed,
13 a brief description of the results of each
14 study, and conclusions drawn from each
15 study; and

16 “(ii) new raw data for each study,
17 which may include, as applicable, tabula-
18 tions of data and results as required under
19 section 814.20(b)(6)(ii) of title 21, Code of
20 Federal Regulations (or any successor reg-
21 ulations); and

22 “(iii) for nonclinical laboratory studies
23 involving the test, if applicable, a state-
24 ment that studies were conducted in com-

1 pliance with applicable good laboratory
2 practices.

3 “(H) To the extent the application seeks
4 authorization to make modifications to the test
5 within the scope of the approval that are other-
6 wise permitted without premarket review under
7 this subchapter, a proposed change protocol
8 that includes validation procedures and accept-
9 ance criteria for anticipated modifications that
10 could be made to the test within the scope of
11 the approval.

12 “(I) Proposed labeling, in accordance with
13 the requirements of section 587L.

14 “(J) Such other data or information as the
15 Secretary may require in accordance with the
16 least burdensome requirements under section
17 587BB(c).

18 “(4) GUIDANCE FOR PREMARKET AND ABBRE-
19 VIATED PREMARKET APPLICATIONS.—In accordance
20 with section 825 of the VALID Act of 2022, the
21 Secretary shall issue draft guidance detailing the in-
22 formation to be provided in a premarket application
23 and special premarket application under this section.
24 The Secretary shall issue final guidance detailing the
25 information to be provided in a premarket applica-

1 tion and special premarket application under this
2 section not later than 1 year prior to the effective
3 date of such Act.

4 “(5) REFUSE TO FILE A PREMARKET OR AB-
5 BREViated PREMARKET APPLICATION.—The Sec-
6 retary may refuse to file an application under this
7 section only for lack of completeness or legibility of
8 the application. If, after receipt of an application
9 under this section, the Secretary refuses to file such
10 an application, the Secretary shall provide to the de-
11 veloper, within 60 calendar days of receipt of such
12 application, a description of the reason for such re-
13 fusal, and identify the information required, if any,
14 to allow for the filing of the application.

15 “(6) SUBSTANTIVE REVIEW FOR DEFICIENT AP-
16 PLICATION.—If, after receipt of an application under
17 this section, the Secretary determines that any por-
18 tion of such application is materially deficient, the
19 Secretary shall provide to the applicant a description
20 of such material deficiencies and the information re-
21 quired to resolve such deficiencies.

22 “(7) INSPECTIONS.—With respect to an appli-
23 cation under paragraph (1), preapproval inspections
24 authorized by an employee of the Food and Drug
25 Administration or a person accredited under section

1 587Q need not occur unless requested by the Sec-
2 retary

3 “(b) ABBREVIATED PREMARKET REVIEW.—

4 “(1) IN GENERAL.—Any developer may file
5 with the Secretary an application for abbreviated
6 premarket approval for—

7 “(A) an instrument;

8 “(B) a specimen receptacle;

9 “(C) an in vitro clinical test that is mod-
10 erate-risk; or

11 “(D) an in vitro clinical test that is deter-
12 mined by the Secretary to be eligible for abbrevi-
13 ated premarket review under section
14 587F(a)(1)(B).

15 “(2) APPLICATION CONTENT.—An application
16 under paragraph (1) shall include—

17 “(A) the information required for applica-
18 tions submitted under subsection (a)(2), except
19 that applications under paragraph (1) need not
20 include—

21 “(i) quality requirement information;

22 or

23 “(ii) raw data, unless explicitly re-
24 quested by the Secretary; and

1 “(B) data, as applicable, to support soft-
2 ware validation, electromagnetic compatibility,
3 and electrical safety, and information dem-
4 onstrating compliance with maintaining quality
5 systems documentation.

6 “(3) SAFETY INFORMATION.—The developer of
7 an in vitro clinical test specimen receptacle reviewed
8 under this subsection shall maintain safety informa-
9 tion for such specimen receptacle.

10 “(4) INSPECTIONS.—With respect to an appli-
11 cation under paragraph (1), preapproval inspections
12 authorized by an employee of the Food and Drug
13 Administration or a person accredited under section
14 587Q need not occur unless requested by the Sec-
15 retary.

16 “(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

17 “(1) IN GENERAL.—A developer of an instru-
18 ment family shall file with the Secretary an applica-
19 tion for premarket approval of one version of an in-
20 strument under this subsection. Any modified
21 versions of the instrument that generate a new in-
22 strument within the same instrument family shall be
23 exempt from premarket review requirements of this
24 section, provided that the developer of such instru-
25 ment or instrument family—

1 “(A) maintains documentation that the
2 new instrument is part of the instrument fam-
3 ily, as defined in section 587;

4 “(B) performs, documents, and maintains
5 a risk assessment (as described in subsection
6 (a)(2)(B)(iv)) of the new instrument compared
7 to the instrument approved under subsection
8 (b) and no new risks are identified;

9 “(C) performs, documents, and maintains
10 validation and verification activities for the new
11 instrument;

12 “(D) makes such documentation available
13 to the Secretary upon request; and

14 “(E) registers and lists the new instrument
15 in accordance with section 587J.

16 “(2) TEST KITS AND TEST PROTOCOLS.—A test
17 kit or test protocol that is approved under this sec-
18 tion for use on an approved instrument or an instru-
19 ment exempt from premarket review, including an
20 instrument within an instrument family under this
21 section, a submission under this section shall not be
22 required for such test kit or test protocol in order
23 for it to be used on a new instrument within its in-
24 strument family, provided that—

1 “(A) use of the test kit or test protocol
2 with the new instrument does not—

3 “(i) change the claims for the test kit
4 or test system described in the protocol,
5 except as applicable, claims regarding an
6 instrument or instruments that can be
7 used with such test kit or test system;

8 “(ii) adversely affect performance of
9 the test kit or test system described in the
10 protocol; or

11 “(iii) cause the test kit or test system
12 described in the test protocol to no longer
13 conform with performance standards re-
14 quired under section 587R or comply with
15 any applicable mitigating measures under
16 section 587E, conditions of approval under
17 subsection (e)(2)(B), or restrictions under
18 section 587O;

19 “(B) the test developer does not identify
20 any new risks for the test kit or test system de-
21 scribed in the test protocol when using the new
22 instrument;

23 “(C) the test developer validates the use of
24 the new instrument with the test kit or the test

1 system described in the test protocol and main-
2 tains validation documentation;

3 “(D) the test kit or test protocol is not in-
4 tended for use—

5 “(i) at the point of care setting or in
6 settings for which a certificate of waiver is
7 in effect under section 353 of the Public
8 Health Service Act;

9 “(ii) without a prescription;

10 “(iii) at home; or

11 “(iv) in testing donors, donations, and
12 recipients of blood, blood components,
13 human cells, tissues, cellular-based prod-
14 ucts, or tissue-based products;

15 “(E) the test developer makes the docu-
16 mentation described under subparagraph (C)
17 available to the Secretary upon request; and

18 “(F) the test developer updates the listing
19 information for the test kit or test protocol, as
20 applicable.

21 “(d) AMENDMENTS TO AN APPLICATION.— An appli-
22 cant shall amend an application submitted under sub-
23 section (a), (b), or (e) if the applicant becomes aware of
24 information that—

1 “(1) could reasonably affect an evaluation of
2 whether the applicable standard has been met; or

3 “(2) could reasonably affect the statement of
4 contraindications, warnings, precautions, and ad-
5 verse reactions in the proposed labeling.

6 “(e) ACTION ON AN APPLICATION FOR PREMARKET
7 APPROVAL.—

8 “(1) REVIEW.—

9 “(A) DISPOSITION.—As promptly as pos-
10 sible, but not later than 90 calendar days after
11 an application under subsection (a) is accepted
12 for submission (unless the Secretary determines
13 that an extension is necessary to review one or
14 more major amendments to the application), or
15 not later than 60 calendar days after an appli-
16 cation under subsection (b) is accepted for sub-
17 mission or a supplemental application under
18 subsection (f) is accepted for submission, the
19 Secretary, after considering any applicable re-
20 port and recommendations pursuant to advisory
21 committees under section 587H, shall issue an
22 order approving the application, unless the Sec-
23 retary finds that the grounds for approval in
24 paragraph (2) are not met.

1 “(B) RELIANCE ON PROPOSED LABEL-
2 ING.—In determining whether to approve or
3 deny an application under paragraph (1), the
4 Secretary shall rely on the [intended/conditions
5 of] use included in the proposed labeling, pro-
6 vided that such labeling is not false or mis-
7 leading based on a fair evaluation of all mate-
8 rial facts.

9 “(2) APPROVAL OF AN APPLICATION.—

10 “(A) IN GENERAL.—The Secretary shall
11 approve an application submitted under sub-
12 section (a) or (b) with respect to an in vitro
13 clinical test if the Secretary finds that the ap-
14 plicable standard is met, and—

15 “(i) the applicant is in compliance
16 with applicable quality requirements in sec-
17 tion 587K;

18 “(ii) the application does not contain
19 a false statement or misrepresentation of
20 material fact;

21 “(iii) based on a fair evaluation of all
22 material facts, the proposed labeling is
23 truthful and non-misleading and complies
24 with the requirements of section 587L;

1 “(iv) the applicant permits, if re-
2 quested, authorized employees of the Food
3 and Drug Administration and persons ac-
4 credited under section 587Q an oppor-
5 tunity to inspect pursuant to section 704;

6 “(v) the test conforms with any appli-
7 cable performance standards required
8 under section 587R and any applicable
9 mitigating measures under section 587E;

10 “(vi) all nonclinical laboratory studies
11 and clinical investigations involving human
12 subjects that are described in the applica-
13 tion were conducted in a manner that
14 meets the applicable requirements of this
15 subchapter; and

16 “(vii) other data and information the
17 Secretary may require under subsection
18 (a)(2)(K) support approval.

19 “(B) CONDITIONS OF APPROVAL.—An
20 order approving an application pursuant to this
21 section may require reasonable conditions of ap-
22 proval for the in vitro clinical test, which may
23 include conformance with applicable mitigating
24 measures under section 587E, restrictions

1 under section 587O, and performance standards
2 under section 587R.

3 “(C) PUBLICATION.—The Secretary shall
4 publish an order for each application approved
5 pursuant to this paragraph on the public
6 website of the Food and Drug Administration
7 and make publicly available a summary of the
8 data used to approve such application, except to
9 the extent the Secretary determines that such
10 order—

11 “(i) contains commercially confidential
12 or trade secret information; or

13 “(ii) if published, would present a risk
14 to national security.

15 “(3) REVIEW OF DENIALS.—An applicant
16 whose application submitted under this section has
17 been denied approval under this subsection may, by
18 petition filed not more than 60 calendar days after
19 the date on which the applicant receives notice of
20 such denial, obtain review of the denial in accord-
21 ance with section 587P.

22 “(f) SUPPLEMENTS TO AN APPROVED APPLICA-
23 TION.—

24 “(1) RISK ANALYSIS.—Prior to implementing
25 any modification to an in vitro clinical test, the hold-

1 er of the application approved under subsection (a)
2 or (b) for such test shall perform risk analyses in ac-
3 cordance with **[section 587J]/[this subsection?]**,
4 unless such modification is included in the change
5 protocol submitted by the applicant and approved
6 under this section or exempt under section 587C.

7 “(2) SUPPLEMENT REQUIREMENT.—

8 “(A) IN GENERAL.—If the holder of an ap-
9 plication of an approved in vitro clinical test
10 makes a modification to such in vitro clinical
11 test, except as provided in subparagraph (C), or
12 otherwise specified by the Secretary, the holder
13 of the application approved under subsection (e)
14 for an in vitro clinical test shall submit a sup-
15 plemental application to the Secretary. The
16 holder of the application may not implement
17 such modification to the in vitro clinical test
18 until such supplemental application is approved.
19 The information required in a supplemental ap-
20 plication is limited to what is needed to support
21 the change.

22 “(B) ADJUSTMENTS TO CHANGE PRO-
23 TOCOL.—The holder of an approved application
24 may submit under this paragraph a supple-
25 mental application to modify the change pro-

1 tocol of the test at any time after the applica-
2 tion is submitted under subsection (a) or (b).

3 “(C) EXCEPTIONS.—Notwithstanding sub-
4 paragraphs (A) and (B), and so long as the
5 holder of an approved application submitted
6 under subsection (a) or (b) for an in vitro clin-
7 ical test does not add a manufacturing site, or
8 change activities at an existing manufacturing
9 site, with respect to the test, the holder of an
10 approved application may, without submission
11 of a supplemental application, implement the
12 following modifications to the test:

13 “(i) Modifications in accordance with
14 an approved change protocol under sub-
15 section (a)(2)(H).

16 “(ii) Modifications that are exempt
17 under section 587C(b).

18 “(D) REPORTING FOR CHANGE PROTOCOL
19 FOR CERTAIN MODIFICATIONS.—The holder of
20 an application approved under subsection (e),
21 with an approved change protocol under sub-
22 section (a)(2)(H) for such in vitro clinical test
23 shall—

24 [“(i) report any modification made
25 pursuant to such change protocol approved

1 under subsection (a)(2)(H) in a submission
2 under section 587J(e)(2)(B); and】

3 【“(ii) include in such report—】

4 【“(I) a description of the modi-
5 fication;】

6 【“(II) the rationale for imple-
7 menting such modification; and】

8 【“(III) as applicable, a summary
9 of the evidence supporting that the
10 test, as modified, meets the applicable
11 standard, complies with performance
12 standards required under section
13 587Q, and complies with any miti-
14 gating measures established under
15 section 587E and any restrictions
16 under section 587N.】

17 “(3) CONTENTS OF SUPPLEMENT.—Unless oth-
18 erwise specified by the Secretary, a supplement
19 under this subsection shall include—

20 “(A) for modifications other than manufac-
21 turing site changes requiring a supplement—

22 “(i) a description of the modification;

23 “(ii) data relevant to the modification
24 to demonstrate that the applicable stand-

1 ard is met, not to exceed data require-
2 ments for the original submission;

3 “ (iii) acceptance criteria; and

4 “ (iv) any revised labeling; and

5 “ (B) for manufacturing site changes—

6 “ (i) the information listed in subpara-
7 graph (A); and

8 “ (ii) information regarding the meth-
9 ods used in, or the facilities or controls
10 used for, the development of the test to
11 demonstrate compliance with the applicable
12 quality requirements under section 587K.

13 “(4) ADDITIONAL DATA.—The Secretary may
14 require, when necessary, data to evaluate a modifica-
15 tion to an in vitro clinical test that is in addition to
16 the data otherwise required under the preceding
17 paragraphs if the data request is in accordance with
18 the least burdensome requirements under section
19 587BB(c).

20 “(5) CONDITIONS OF APPROVAL.—In an order
21 approving a supplement under this subsection, the
22 Secretary may require conditions of approval for the
23 in vitro clinical test, including compliance with re-
24 strictions under section 587O and conformance to
25 performance standards under section 587R.

1 “(6) APPROVAL.—The Secretary shall approve
2 a supplement under this subsection if—

3 “(A) the data demonstrate that the modi-
4 fied in vitro clinical test meets the applicable
5 standard; and

6 “(B) the holder of the application approved
7 under subsection (e) for the test has dem-
8 onstrated compliance with applicable quality
9 and inspection requirements, as applicable and
10 appropriate.

11 “(7) PUBLICATION.—The Secretary shall pub-
12 lish on the public website of the Food and Drug Ad-
13 ministration notice of any order approving a supple-
14 ment under this subsection, except that such publi-
15 cation shall exclude—

16 “(A) commercial confidential or trade se-
17 cret information; and

18 “(B) any other information that the Sec-
19 retary determines to relate to national security
20 or countermeasures or to be restricted from dis-
21 closure pursuant to another provision of law.

22 “(8) REVIEW OF DENIAL.—An applicant whose
23 supplement under this subsection has been denied
24 approval may, by petition filed on or before the 60th
25 calendar day after the date upon which the applicant

1 receives notice of such denial, obtain review of the
2 denial in accordance with section 587P.

3 “(g) WITHDRAWAL AND TEMPORARY SUSPENSION
4 OF APPROVAL.—

5 “(1) ORDER WITHDRAWING APPROVAL.—

6 “(A) IN GENERAL.—The Secretary may,
7 after providing due notice and an opportunity
8 for an informal hearing to the holder of an ap-
9 proved application for an in vitro clinical test
10 under this section, issue an order withdrawing
11 approval of the application if the Secretary
12 finds that—

13 “(i) the grounds for approval under
14 subsection (e) are no longer met;

15 “(ii) there is a reasonable likelihood
16 that the test would cause death or serious
17 adverse health consequences, including by
18 causing the absence, significant delay, or
19 discontinuation of life-saving or life sus-
20 taining medical treatment;

21 “(iii) the holder of the approved appli-
22 cation—

23 “(I) has failed to, or repeatedly
24 or deliberately failed to, maintain
25 records to make reports, as required

1 under section 587M **【***this is also ref-*
2 *erenced in subclause (IV)—cover all of*
3 *adverse reporting requirements here,*
4 *together instead?* **】**;

5 “(II) has refused to permit ac-
6 cess to, or copying or verification of
7 such records, as required under sec-
8 tion 704;

9 “(III) has not complied with the
10 requirements of section 587K; or

11 “(IV) has not complied with any
12 mitigating measure required under
13 section 587E, restriction under sec-
14 tion 587O, or adverse event reporting
15 requirement under section 587M; or

16 “(iv) the labeling of such in vitro clin-
17 ical test, based on a fair evaluation of all
18 material facts, is false or misleading in any
19 particular and was not corrected within a
20 reasonable time after receipt of written no-
21 tice from the Secretary of such fact.

22 “(B) CONTENT.—An order under subpara-
23 graph (A) withdrawing approval of an applica-
24 tion shall state each ground for withdrawal and

1 shall notify the holder of such application 60
2 calendar days prior to issuing such order.

3 “(C) PUBLICATION.—The Secretary shall
4 publish any order under subparagraph (A) on
5 the public website of the Food and Drug Ad-
6 ministration, except that such publication shall
7 exclude—

8 “(i) commercial confidential or trade
9 secret information; and

10 “(ii) any other information that the
11 Secretary determines, if published, would
12 present a risk to national security.

13 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
14 after providing due notice and an opportunity for an
15 informal hearing to the holder of an approved appli-
16 cation for an in vitro clinical test under this section,
17 the Secretary determines, based on scientific evi-
18 dence, that there is a reasonable likelihood that the
19 in vitro clinical test would cause death or serious ad-
20 verse health consequences, such as by causing the
21 absence, significant delay, or discontinuation of life-
22 saving or life-sustaining medical treatment, the Sec-
23 retary shall, by order, temporarily suspend the ap-
24 proval of the application. If the Secretary issues
25 such an order, the Secretary shall proceed expedi-

1 tiously under paragraph (1) to withdraw approval of
2 such application.

3 “(3) APPEAL WITHDRAWING APPROVAL AND
4 ORDERS OF TEMPORARY SUSPENSIONS.—An order of
5 withdrawal or an order of temporary suspension may
6 be appealed under 587P.

7 **“SEC. 587C. EXEMPTIONS.**

8 “(a) IN GENERAL.—The following in vitro clinical
9 tests are exempt from premarket review under section
10 587B, and may be lawfully marketed subject to other ap-
11 plicable requirements of this Act:

12 “(1) TESTS EXEMPT FROM SECTION 510(k).—

13 “(A) EXEMPTION.—An in vitro clinical
14 test is exempt from premarket review under
15 section 587B and may be lawfully marketed
16 subject to the other applicable requirements of
17 this Act, if the in vitro clinical test—

18 “(i)(I)(aa) was offered for clinical use
19 prior to the date of enactment of the
20 VALID Act of 2022; and

21 “(bb) immediately prior to such date
22 of enactment was exempt pursuant to sub-
23 section (l) or (m)(2) of section 510 from
24 the requirements for submission of a re-
25 port under section 510(k); or

1 “(II)(aa) was not offered for clinical
2 use prior to such date of enactment;

3 “(bb) is not a test platform; and

4 “(cc) falls within a category of tests
5 that was exempt from the requirements for
6 submission of a report under section
7 510(k) as of such date of enactment (in-
8 cluding class II devices and excluding class
9 I devices described in section 510(l));

10 **【“(ii) meets the applicable standard
11 as described in section 587(2);】**

12 **【“(iii) is not offered with labeling and
13 advertising that is false or misleading;
14 and】**

15 **【“(iv) is not likely to cause or con-
16 tribute to serious adverse health con-
17 sequences.】**

18 “(B) EFFECT ON SPECIAL CONTROLS.—
19 For any in vitro clinical test, or category of in
20 vitro clinical tests, that is exempt from pre-
21 market review based on the criteria in subpara-
22 graph (A), any special control that applied to a
23 device within a predecessor category imme-
24 diately prior to the date of enactment of the
25 VALID Act of 2022 shall be deemed a miti-

1 gating measure applicable under section 587E
2 to an in vitro clinical test within the successor
3 category, except to the extent such mitigating
4 measure is withdrawn or changed in accordance
5 with section 587E.

6 “(C) NEAR-PATIENT TESTING.—Not later
7 than 1 year after the date of enactment of the
8 VALID Act of 2022, the Secretary shall issue
9 draft guidance indicating categories of tests
10 that shall be exempt from premarket review
11 under section 587B when offered for near-pa-
12 tient testing (point of care), which were not ex-
13 empt from submission of a report under section
14 510(k) pursuant to subsection (l) or (m)(2) of
15 section 510 and regulations imposing limita-
16 tions on exemption for in vitro devices intended
17 for near-patient testing (point of care).

18 “(2) LOW-RISK TESTS.—

19 “(A) EXEMPTION.—An in vitro clinical
20 test is exempt from premarket review under
21 section 587B and may be lawfully marketed
22 subject to the other applicable requirements of
23 this Act, including section 587J(b)(6), if such
24 test meets the definition of low-risk under sec-
25 tion 587 and if the developer of the test—

1 “(i) maintains documentation dem-
2 onstrating that the in vitro clinical test
3 meets and continues to meet the criteria
4 set forth in paragraph (2); and

5 “(ii) makes such documentation avail-
6 able to the Secretary upon request.

7 “(B) CRITERIA FOR EXEMPTION.—An in
8 vitro clinical test is exempt as specified in sub-
9 paragraph (A) if—

10 “(i) the in vitro clinical test meets the
11 applicable standard as described in 587(2);

12 “(ii) the labeling and advertising are
13 not false or misleading;

14 “(iii) the in vitro clinical test is not
15 likely to cause or contribute to serious ad-
16 verse health consequences; and

17 “(iv) the in vitro clinical test is listed
18 pursuant to section 587J or falls within a
19 category of tests listed as described in sub-
20 paragraph (C).

21 “(C) LIST OF LOW-RISK TESTS.—

22 “(i) IN GENERAL.—The Secretary
23 shall maintain, and make publicly available
24 on the website of the Food and Drug Ad-
25 ministration, a list of in vitro clinical tests,

1 and categories of in vitro clinical tests,
2 that are low-risk in vitro clinical tests for
3 purposes of the exemption under this para-
4 graph.

5 “(ii) INCLUSION.—The list under
6 clause (i) shall consist of—

7 “(I) all in vitro clinical tests and
8 categories of in vitro clinical tests that
9 are exempt from premarket review
10 pursuant to subsection (d)(1) or
11 (d)(3); and

12 “(II) all in vitro clinical tests and
13 categories of in vitro clinical tests that
14 are designated by the Secretary pur-
15 suant to subparagraph (C) as low-risk
16 for purposes of this paragraph.

17 “(D) DESIGNATION OF TESTS AND CAT-
18 EGORIES.—Without regard to subchapter II of
19 chapter 5 of title 5, United States Code, the
20 Secretary may designate, in addition to the
21 tests and categories described in subparagraph
22 (C)(i), additional in vitro clinical tests, and cat-
23 egories of in vitro clinical tests, as low-risk in
24 vitro clinical tests for purposes of the exemption
25 under this paragraph. The Secretary may make

1 such a designation on the Secretary’s own ini-
2 tiative or in response to a request by a devel-
3 oper pursuant to subsection (a) or (b) of section
4 587F. In making such a designation for a test
5 or category of tests, the Secretary shall con-
6 sider—

7 “(i) whether the test, or category of
8 tests, is low-risk;

9 “(ii) the existence of and ability to de-
10 velop mitigating measures sufficient for
11 such test category to meet the low-risk
12 standard; and

13 “(iii) such other factors as the Sec-
14 retary determines to be appropriate for the
15 protection of the public health.

16 “(3) HUMANITARIAN TEST EXEMPTION.—

17 “(A) IN GENERAL.—An in vitro clinical
18 test that meets the criteria under subparagraph
19 (B) is exempt from premarket review under sec-
20 tion 587B and may be lawfully offered subject
21 to the other applicable requirements of this sub-
22 chapter, if the developer of the test—

23 “(i) maintains documentation (which
24 may include literature citations in special-
25 ized medical journals, textbooks, special-

1 ized medical society proceedings, and gov-
2 ernmental statistics publications, or, if no
3 such studies or literature citations exist,
4 credible conclusions from appropriate re-
5 search or surveys) demonstrating that such
6 test meets and continues to meet the cri-
7 teria described in this subsection; and

8 “(ii) makes such documentation avail-
9 able to the Secretary upon request.

10 “(B) CRITERIA FOR EXEMPTION.—An in
11 vitro clinical test is exempt as described in sub-
12 paragraph (A) if—

13 “(i) the in vitro clinical test is in-
14 tended by the developer for use for a diag-
15 nostic purpose for a disease or condition
16 **【that affects】** not more than 10,000 (or
17 such other higher number determined by
18 the Secretary) individuals in the United
19 States per year; and

20 “(ii) the in vitro clinical test meets
21 the applicable standard described in sec-
22 tion 587(2);

23 “(iii) the labeling and advertising for
24 the in vitro clinical test are not false or
25 misleading;

1 “(iv) the in vitro clinical test is not
2 likely to cause or contribute to serious
3 health consequences;

4 **【“(v) the in vitro clinical test is not**
5 intended to diagnose a contagious disease
6 or condition for which prompt and accu-
7 rate diagnosis offers the opportunity to
8 mitigate a public health impact of the dis-
9 ease or condition; and**】**

10 **【“(vi) the in vitro clinical test is not**
11 intended for screening.**】**

12 “(C) EXCEPTION FOR CERTAIN TESTS.—
13 An in vitro clinical test intended to inform the
14 use of a specific individual or specific type of bi-
15 ological product, drug, or device shall be eligible
16 for an exemption from premarket review under
17 this subsection only if, the developer submits a
18 request under subsection (m) for informal feed-
19 back and the Secretary determines that such in
20 vitro clinical test is eligible for an exemption
21 from premarket review under this subsection.

22 “(4) CUSTOM TESTS AND LOW-VOLUME
23 TESTS.—An in vitro clinical test is exempt from pre-
24 market review under section 587B, quality require-
25 ments under section 587K, and listing requirements

1 under section 587J, and may be lawfully marketed
2 subject to the other applicable requirements of this
3 Act, if—

4 “(A) such in vitro clinical test—

5 “(i) is a test protocol that describes a
6 test system performed for not more than 5
7 patients per year (or such other higher
8 number determined by the Secretary), per-
9 formed in a laboratory certified by the Sec-
10 retary under section 353 of the Public
11 Health Service Act (42 U.S.C. 263a)
12 that—

13 “(I) meets the requirements to
14 perform tests of high-complexity in
15 which the test protocol was developed;
16 or

17 “(II) meets the requirements to
18 perform tests of high-complexity with-
19 in the same corporate organization
20 and having common ownership by the
21 same parent corporation as the lab-
22 oratory in which such test protocol
23 was developed; or

24 “(ii) is an in vitro clinical test devel-
25 oped or modified to diagnose a unique pa-

1 thology or physical condition of a specific
2 patient or patients, upon order of a health
3 professional or other specially qualified
4 person designated under regulations, for
5 which no other in vitro clinical test is com-
6 mercially available in the United States,
7 and is—

8 “(I) not intended for use with re-
9 spect to more than 5 (or such other
10 higher number determined by the Sec-
11 retary) other patients; and

12 “(II) after the development of
13 such test, not included in any test
14 menu or template test report or other
15 promotional materials, and is not oth-
16 erwise advertised; and

17 “(B) the developer of the in vitro clinical
18 test—

19 “(i) maintains documentation dem-
20 onstrating that such test meets the appli-
21 cable criteria described in subparagraph
22 (A);

23 “(ii) makes such documentation, such
24 as a prescription order requesting the cus-

1 tom test for an individual patient, available
2 to the Secretary upon request; and

3 “(iii) informs the Secretary, on an an-
4 nual basis, in a manner prescribed by the
5 Secretary by guidance, that such test was
6 offered.

7 “(5) IN VITRO CLINICAL TESTS UNDER A TECH-
8 NOLOGY CERTIFICATION ORDER.—An in vitro clin-
9 ical test that is within the scope of a technology cer-
10 tification order, as described in section 587D(a), is
11 exempt from premarket review under section
12 587B.”.

13 “(6) MODIFIED TESTS.—

14 “(A) IN GENERAL.—An in vitro clinical
15 test that is modified is exempt from premarket
16 review under section 587B if—

17 “(i) the modification does not—

18 “(I) affect the analytical or clin-
19 ical validity of such test or change in
20 intended use, unless provided for
21 under an approved change protocol
22 under section 587B(a)(2)(H);

23 “(II) cause the test to no longer
24 comply with applicable mitigating

1 measures under section 587E or re-
2 strictions under section 587O;

3 “(III) as applicable, affect the
4 safety of a specimen receptacle for a
5 purpose described in section
6 201(ss)(1);

7 **【“(IV) change performance or
8 performance claims; or】**

9 **【“(V) change the safety of the in
10 vitro clinical test for individuals who
11 come in contact with the in vitro clin-
12 ical test;】**

13 **【“(ii) the test meets the applicable
14 standard as described in section 587(2);】**

15 **【“(iii) the labeling and advertising are
16 not false or misleading;】**

17 **【“(iv) the test is not likely to cause or
18 contribute to serious adverse health con-
19 sequences; and】**

20 “(v) the modification is a labeling
21 change that is appropriate to address a
22 safety concern, except such labeling
23 changes that include—

1 “(I) a change to the performance
2 claims made with respect to the test;
3 or

4 “(II) a change that adversely af-
5 fects performance.

6 “(B) LABELING CHANGES.—Labeling
7 changes shall be approved through a supple-
8 mental application under section 587B(h), ex-
9 cept as described in subparagraph (A)(v).

10 “(C) DOCUMENTATION.—A person who
11 modifies an in vitro clinical test in a manner
12 that is a modification described in subpara-
13 graph (A) shall—

14 “(i) document the modification that
15 was made and the basis for determining
16 that the modification, considering the
17 changes individually and collectively, is a
18 type of modification described in subpara-
19 graph (A); and

20 “(ii) provide such documentation to
21 the Secretary upon request or inspection.

22 “(b) MANUAL TESTS.—

23 “(1) EXEMPTION.—An in vitro clinical test is
24 exempt from all requirements of this subchapter if
25 the output of such in vitro clinical test is the result

1 of direct, manual observation, without the use of
2 automated instrumentation or software for inter-
3 mediate or final interpretation, by a qualified labora-
4 tory professional, and such in vitro clinical test—

5 “(A) is designed, manufactured, and used
6 within a single clinical laboratory for which a
7 certificate is in effect under section 353 of the
8 Public Health Service Act that meets the re-
9 quirements under section 353 for performing
10 high-complexity testing;

11 “(B) is not a high-risk test, or is a high-
12 risk test that the Secretary has determined
13 meets at least one condition in subparagraph
14 (B) and is otherwise appropriate for this ex-
15 emption; and

16 “(C) is not intended for testing donors, do-
17 nations, or recipients of blood, blood compo-
18 nents, human cells, tissues, cellular-based prod-
19 ucts, or tissue-based products.

20 “(2) HIGH-RISK TEST LIMITATION OR CONDI-
21 TION.—A high-risk test may be exempt under sub-
22 paragraph (A) from the requirements of this sub-
23 chapter only if—

24 “(A) no component or part of such test, in-
25 cluding any reagent, is introduced into inter-

1 state commerce under the exemption under
2 paragraph (5), and any article for taking or de-
3 riving specimens from the human body used in
4 conjunction with the test remains subject to the
5 requirements of this subchapter; or

6 “(B) the test has been developed in accord-
7 ance with the applicable test design and quality
8 requirements under section 587J.

9 “(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

10 “(1) IN GENERAL.—The provisions of this sub-
11 chapter shall not apply to a test intended by the de-
12 veloper to be used solely for public health surveil-
13 lance activities, including the collection and testing
14 of information or biospecimens, conducted, sup-
15 ported, requested, ordered, required, or authorized
16 by a public health authority, and including activities
17 associated with providing timely situational aware-
18 ness and priority-setting during the course of a
19 threat to the public health (including natural or
20 man-made disasters and deliberate attacks on the
21 United States).

22 “(2) LIMITATION.—Subparagraph (A) shall
23 apply with respect to public health surveillance ac-
24 tivities described in such subparagraph only if such
25 activities are necessary to allow a public health au-

1 thority to identify, monitor, assess, or investigate po-
2 tential public health signals, onsets of disease out-
3 breaks, or conditions of public health importance
4 (including trends, risk factors, patterns in diseases,
5 and increases in injuries from using consumer prod-
6 ucts).

7 “(3) EXCLUSION.—An in vitro clinical test is
8 not excluded from the provisions of this subchapter
9 pursuant to this paragraph if such test is intended
10 for use in making clinical decisions for individual pa-
11 tients.

12 “(d) GENERAL LABORATORY EQUIPMENT.—Any in-
13 strument that does not produce an analytical result, and
14 that functions as a component of pre-analytical procedures
15 related to in vitro clinical tests, is not subject to the re-
16 quirements of this subchapter, provided that the instru-
17 ment is operating in a clinical laboratory that is certified
18 under section 353 of the Public Health Service Act.

19 “(e) COMPONENTS AND PARTS.—

20 “(1) IN GENERAL.—Subject to paragraph (2), a
21 component or part described in section
22 201(ss)(2)(E) is exempt from the requirements of
23 this subchapter if it is—

24 “(A) intended for further development as
25 described in paragraph (3); or

1 “(B) otherwise to be regulated based on its
2 risk when used as intended by the developer,
3 notwithstanding its subsequent use by a devel-
4 oper as a component, part, or raw material of
5 another in vitro clinical test.

6 “(2) INAPPLICABILITY TO OTHER TESTS.—Not-
7 withstanding paragraph (1), an in vitro clinical test
8 that is described in section 201(ss)(1)(B) and that
9 uses a component or part described in such subpara-
10 graph shall be subject to the requirements of this
11 subchapter, unless the test is otherwise exempt
12 under this section.

13 “(3) FURTHER DEVELOPMENT.—A component,
14 part, or raw material (as described in paragraph
15 (1)) is intended for further development (for pur-
16 poses of such paragraph) if—

17 “(A) it is intended solely for use in the de-
18 velopment of another in vitro clinical test; and

19 “(B) in the case of such a test that is in-
20 troduced or delivered for introduction into
21 interstate commerce after the date of enactment
22 of the VALID Act of 2022, the labeling of such
23 test bears the following statement: ‘This prod-
24 uct is intended solely for further development of
25 an in vitro clinical test and is exempt from

1 FDA regulation. This product must be evalu-
2 ated by the in vitro clinical test developer if it
3 is used with or in the development of an in vitro
4 clinical test.’.

5 “(f) GENERAL EXEMPTION AUTHORITY.—The Sec-
6 retary may, by order published in the Federal Register
7 following notice and an opportunity for comment, exempt
8 a class of persons from any section under this subchapter
9 upon a finding that such exemption is appropriate for the
10 protection of the public health and other relevant consider-
11 ations.

12 “(g) EXEMPTION FROM THE FFDCA.—An in vitro
13 clinical test that is intended solely for use in forensic anal-
14 ysis, law enforcement activity, or employment purposes is
15 exempt from the requirements of this Act. An in vitro clin-
16 ical test that is intended for use in making clinical deci-
17 sions for individual patients, or whose individually identifi-
18 able results may be reported back to an individual patient
19 or the patient’s health care provider, even if also intended
20 for law enforcement or employment testing purposes, is
21 not intended solely for use in law enforcement or employ-
22 ment testing for purposes of this subsection.

23 “(h) REVOCATION.—

24 “(1) IN GENERAL.—The Secretary may revoke
25 any exemption with respect to in vitro clinical tests

1 with the same intended use if new clinical informa-
2 tion indicates that the exemption of an in vitro clin-
3 ical test or tests from premarket review under sec-
4 tion 587B has a reasonable probability of severe ad-
5 verse health consequences, including the absence,
6 delay, or discontinuation of appropriate medical
7 treatment.

8 “(2) PROCESS.—Any action under paragraph
9 (1) shall be made by publication of a notice of such
10 proposed action on the website of the Food and
11 Drug Administration, the consideration of comments
12 to a public docket on such proposal, and publication
13 of a final action on such website within 60 calendar
14 days of the close of the comment period posted to
15 such public docket, notwithstanding subchapter II of
16 chapter 5 of title 5, United States Code.

17 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

18 “(a) DEFINITIONS.—In this section:

19 “(1) ELIGIBLE IN VITRO CLINICAL TEST.—The
20 term ‘eligible in vitro clinical test’ means an in vitro
21 clinical test that is not—

22 “(A) a component or part of an in vitro
23 clinical test as described in section
24 201(ss)(2)(E);

1 “(B) an instrument under section
2 201(ss)(2)(B);

3 “(C) a specimen receptacle under section
4 201(ss)(2)(C);

5 “(D) an in vitro clinical test, including re-
6 agents used in such tests, intended for use for
7 testing donors, donations, and recipients of
8 blood, blood components, human cells, tissues,
9 cellular-based products, or tissue-based prod-
10 ucts;

11 “(E) high-risk;

12 “(F) a combination product unless such
13 test has been determined to be eligible to be in-
14 troduced into interstate commerce under a tech-
15 nology certification order pursuant to the regu-
16 latory pathway designation process described in
17 section 587F, or as described in subsection (k);
18 or

19 “(G) a first-of-a-kind in vitro clinical test,
20 unless such test has been determined to be eli-
21 gible to be introduced into interstate commerce
22 under a technology certification order pursuant
23 to the regulatory pathway designation process
24 described in section 587F, or as described in
25 subsection (k).

1 “(2) ELIGIBLE PERSON.—The term ‘eligible
2 person’ means an in vitro clinical test developer un-
3 less such developer—

4 “(A) is a laboratory subject to section 353
5 of the Public Health Service Act and does not
6 have in effect a certificate applicable to the cat-
7 egory of laboratory examination or other proce-
8 dure;

9 “(B) was a laboratory, or an owner or op-
10 erator or any employee of a laboratory, found
11 to have committed a significant violation of sec-
12 tion 353 of the Public Health Service Act that
13 resulted in a suspended, revoked, or limited cer-
14 tificate within the 2-year period preceding the
15 date of the submission of the application for a
16 technology certificate under subsection (c) and
17 such violation has not been resolved; or

18 “(C) has been found to have submitted in-
19 formation to the Secretary, or otherwise dis-
20 seminated information, that—

21 “(i) made false or misleading state-
22 ments relevant to the requirements of this
23 subchapter; or

24 “(ii) violated any requirement of this
25 Act, where such violation exposed individ-

1 uals to serious risk of illness, injury, or
2 death, unless—

3 “(I) such violation has been re-
4 solved; or

5 “(II) such violation is not perti-
6 nent to any in vitro clinical test within
7 the scope of the technology certifi-
8 cation that such developer seeks.

9 “(b) APPLICABILITY.—

10 “(1) IN GENERAL.—An in vitro clinical test is
11 not subject to section 587B and may be introduced
12 into interstate commerce if the in vitro clinical
13 test—

14 “(A) is an eligible in vitro clinical test;

15 “(B) is developed by an eligible person;

16 “(C) falls within the scope of a technology
17 certification order issued under this section and
18 that is in effect; and

19 “(D) complies with the requirements of the
20 technology certification order, including with
21 applicable mitigating measures under section
22 587E, restrictions under section 587O, and per-
23 formance standards under section 587R.

24 “(2) SCOPE.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), the scope of a technology certifi-
3 cation order issued under this section shall be
4 no broader than—

5 “(i) a single technology type; or

6 “(ii) a fixed combination of tech-
7 nologies where multiple in vitro clinical
8 tests utilizing the technology do not signifi-
9 cantly differ in control mechanisms, energy
10 sources, or operating principles and for
11 which development, including design, and
12 analytical and clinical validation, of the in
13 vitro clinical tests would be addressed
14 through similar procedures.

15 **【“(B) INCLUSIONS.—**Notwithstanding sub-
16 paragraph (A), the scope of a technology certifi-
17 cation order issued under this section may be
18 for one fixed combination of technology types if
19 the Secretary determines appropriate and pro-
20 mulgates regulations establishing criteria and
21 procedures for a technology certification order
22 for a fixed combination of technology types.】

23 “(C) TECHNOLOGY TYPE.—A technology
24 type described in this paragraph may include
25 clot detection, colorimetric (non-immunoassay),

1 electrochemical (non-immunoassay), enzymatic
2 (non-immunoassay), flow cytometry,
3 fluorometry (non-immunoassay), immunoassay,
4 mass spectrometry or chromatography, micro-
5 bial culture, next generation sequencing,
6 nephelometric or turbidimetric (non-
7 immunoassay), singleplex or multiplex non-NGS
8 nucleic acid analysis, signal-based technology,
9 spectroscopy, and any other technology, as the
10 Secretary determines appropriate.

11 “(c) APPLICATION FOR TECHNOLOGY CERTIFI-
12 CATION.—

13 “(1) IN GENERAL.—A developer seeking a tech-
14 nology certification order shall submit an application
15 under this subsection, which shall contain the infor-
16 mation specified under paragraph (2).

17 “(2) CONTENT OF APPLICATION.—A developer
18 that submits an application for a technology certifi-
19 cation shall include all necessary information to
20 make a showing that all eligible in vitro clinical tests
21 developed within the scope of the technology certifi-
22 cation order will meet the applicable standard, in-
23 cluding—

24 “(A) the name and address of the devel-
25 oper;

1 “(B) a table of contents for the application
2 and the identification of the information the de-
3 veloper claims as trade secret or confidential
4 commercial or financial information;

5 “(C) the signature of the individual filing
6 the application or an authorized representative;

7 “(D) a statement identifying the scope of
8 the proposed technology certification intended
9 to be introduced into interstate commerce under
10 the application;

11 “(E) information establishing that the de-
12 veloper submitting the application is an eligible
13 person;

14 “(F) information showing that eligible in
15 vitro clinical tests covered under the technology
16 certification will conform to the applicable qual-
17 ity requirements of section 587K with respect
18 to—

19 “(i) design controls, including related
20 purchasing controls and acceptance activi-
21 ties;

22 “(ii) complaint investigation, adverse
23 event reporting, and corrections and re-
24 movals; and

25 “(iii) process validation, as applicable;

1 【“(G) procedures for analytical validation,
2 including all procedures for validation,
3 verification, and acceptance criteria, and an ex-
4 planation as to how such procedures, when
5 used, provide a reasonable assurance of analyt-
6 ical validity of eligible in vitro clinical tests
7 within the proposed scope of the technology cer-
8 tification order;】

9 【“(H) procedures for clinical validation,
10 including all procedures for validation,
11 verification, and acceptance criteria, and an ex-
12 planation as to how such procedures, when
13 used, provide a reasonable assurance of clinical
14 validity of eligible in vitro clinical tests within
15 the proposed scope of the technology certifi-
16 cation order;】

17 【“(I) procedures, as applicable, that pro-
18 vide a reasonable assurance that in vitro clinical
19 tests covered by the technology certification
20 order are safe for individuals who come into
21 contact with in vitro clinical tests covered by
22 such order;】

23 【“(J) a proposed listing submission under
24 section 587J(b) for in vitro clinical tests that
25 the developer intends to introduce into inter-

1 state commerce upon receiving a technology cer-
2 tification order], which shall not be construed
3 to limit the developer from introducing addi-
4 tional tests not included in such submission
5 under the same technology certification
6 order];]

7 “(K) information concerning one or more
8 representative in vitro clinical tests, including—

9 “(i) a test within the scope of the
10 technology certification application with
11 the appropriate analytical complexity at
12 the time of the submission of the applica-
13 tion under this section to serve as the rep-
14 resentative test and validate and run with-
15 in the developer’s stated scope;

16 “(ii) the information specified in sub-
17 section (a) or (b) of section 587B, as ap-
18 plicable, for the representative in vitro clin-
19 ical test or tests, including information and
20 data required pursuant to subsection
21 (a)(2)(G) of section 587B, unless the Sec-
22 retary determines that such information is
23 not necessary;

24 “(iii) a summary of a risk assessment
25 of the in vitro clinical test;

1 “(iv) an explanation of the choice of
2 the representative in vitro clinical test or
3 tests for the technology certification appli-
4 cation and how such test adequately dem-
5 onstrates the range of procedures that the
6 developer includes in the application under
7 subparagraphs **[(F), (G), (H), (I)],** and
8 **(J)]**; and

9 “(v) a brief explanation of the ways in
10 which the procedures included in the appli-
11 cation under subparagraphs **[(F), (G),**
12 **(H), (I)],** and **(J)]** have been applied to
13 the representative in vitro clinical test or
14 tests; and

15 “(L) such other information necessary to
16 grant a technology certification order as the
17 Secretary may determine necessary.

18 “(3) REFERENCE TO EXISTING APPLICA-
19 TIONS.—With respect to the content requirements in
20 the technology certification application described in
21 paragraph (2), a developer may incorporate by ref-
22 erence any content of an application previously sub-
23 mitted by the developer.

24 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY
25 CERTIFICATION.—

1 “(1) SECRETARY RESPONSE.—

2 “(A) IN GENERAL.—As promptly as prac-
3 ticable, and not later than 90 days after receipt
4 of an application under subsection (c), the Sec-
5 retary shall—

6 “(i) issue a technology certification
7 order granting the application, which shall
8 specify the scope of the technology certifi-
9 cation, if the Secretary finds that all of the
10 grounds in paragraph (3) are met; or

11 “(ii) deny the application if the Sec-
12 retary finds (and sets forth the basis of
13 such finding as part of or accompanying
14 such denial) that one or more grounds for
15 granting the application specified in para-
16 graph (3) are not met.

17 “(B) EXTENSION.—The timeline described
18 in subparagraph (A) may be extended by mu-
19 tual agreement between the Secretary and the
20 applicant.

21 “(2) DEFICIENT APPLICATIONS.—

22 “(A) IN GENERAL.—If, after receipt of an
23 application under this section, the Secretary de-
24 termines that any portion of such application is
25 deficient, the Secretary, not later than 60 days

1 after receipt of such application, shall provide
2 to the applicant a description of such defi-
3 ciencies and identify the information required to
4 resolve such deficiencies.

5 “(B) CONVERTING TO PREMARKET APPLI-
6 CATIONS.—When responding to the deficiency
7 letter, the developer may convert the application
8 for technology certification under subsection (c)
9 into a premarket application under section
10 587B.

11 “(3) TECHNOLOGY CERTIFICATION ORDER.—
12 The Secretary shall issue an order granting a tech-
13 nology certification under this section if, on the
14 basis of the information submitted to the Secretary
15 as part of the application and any other information
16 with respect to such applicant, the Secretary finds
17 that—

18 [“(A) there is a showing that in vitro clin-
19 ical tests within the scope of the technology cer-
20 tification order will meet the applicable stand-
21 ard—]

22 [“(i) in accordance with subsection
23 (c)(2)(G), there is a showing of reasonable
24 assurance of analytical validity for eligible
25 in vitro clinical tests within the scope of

1 the technology certification, as evidenced
2 by the procedures for analytical valida-
3 tion;】

4 【“(ii) in accordance with subsection
5 (c)(2)(H), there is a showing of reasonable
6 assurance of clinical validity for eligible in
7 vitro clinical tests within the proposed
8 scope of the technology certification, as
9 evidenced by the clinical program, includ-
10 ing procedures for clinical validation; and】

11 【“(iii) in accordance with subsection
12 (c)(2)(I), there is a showing of reasonable
13 assurance that all eligible in vitro clinical
14 tests within the scope of the technology
15 certification are safe for the individuals
16 who come into contact with the in vitro
17 clinical test;】

18 “(B) the methods used in, and the facili-
19 ties or controls used for, the development of eli-
20 gible in vitro clinical tests covered by the pro-
21 posed scope of the technology certification con-
22 form to the applicable requirements of section
23 587K with respect to—

1 “(i) design controls, including related
2 purchasing controls and acceptance activi-
3 ties;

4 “(ii) complaint investigation, adverse
5 event reporting, and corrections and re-
6 movals; and

7 “(iii) process validation, as applicable;

8 “(C) based on a fair evaluation of all mate-
9 rial facts, the applicant’s proposed labeling and
10 advertising are not false or misleading in any
11 particular;

12 “(D) the application does not contain a
13 false statement of material fact;

14 “(E) there is a showing that the represent-
15 ative in vitro clinical test or tests—

16 “(i) meet the applicable standard for
17 such order; and

18 “(ii) reasonably represent the range of
19 procedures for analytical validation and
20 clinical validation included in the applica-
21 tion, as applicable;

22 “(F) the applicant has agreed to permit,
23 upon request, authorized employees of the Food
24 and Drug Administration or persons accredited,
25 or recognized under this Act, an opportunity to

1 inspect at a reasonable time and in a reason-
2 able manner the facilities and all pertinent
3 equipment, finished and unfinished materials,
4 containers, and labeling therein, including all
5 things (including records, files, papers, and con-
6 trols) bearing on whether an in vitro clinical
7 test is adulterated, misbranded, or otherwise in
8 violation of this Act, and permits such author-
9 ized employees or persons accredited under this
10 Act to view and to copy and verify all records
11 pertinent to the application and the in vitro
12 clinical test; and

13 **【“(G) based on other data and information**
14 **the Secretary may require under subsection**
15 **(c)(2)(L), the Secretary finds that such data**
16 **and information support granting a technology**
17 **certification order.】**

18 “(4) REVIEW OF DENIALS.—An applicant
19 whose application has been denied under this sub-
20 section may obtain review of such denial under sec-
21 tion 587P.

22 “(e) SUPPLEMENTS.—

23 “(1) SUPPLEMENTAL APPLICATIONS.—

24 “(A) IN GENERAL.—With respect to any of
25 the following changes related to an in vitro clin-

1 ical test under a technology certification order,
2 a supplemental application to a technology cer-
3 tification order shall be submitted by the holder
4 of the technology certification order describing
5 such proposed changes, prior to introducing the
6 in vitro clinical test that is the subject of the
7 technology certification order into interstate
8 commerce—

9 “(i) any significant change to the pro-
10 cedures provided in support of the applica-
11 tion for technology certification submitted
12 under subparagraph (G), (H), or (I) of
13 subsection (c)(2); or

14 “(ii) any significant change to the
15 procedures provided in support of the ap-
16 plication for technology certification sub-
17 mitted under subparagraph (F) of sub-
18 section (c)(2).

19 “(B) SECRETARY ACTION ON SUPPLE-
20 MENTAL APPLICATIONS.—Any action by the
21 Secretary on a supplemental application shall
22 be in accordance with subsection (d), and any
23 order resulting from such supplement shall be
24 treated as an amendment to a technology cer-
25 tification order.

1 “(2) CONTENT OF APPLICATION.—

2 “(A) IN GENERAL.—A supplemental appli-
3 cation for a change to an in vitro clinical test
4 under a technology certification order shall—

5 “(i) contain all necessary information
6 to make a showing that any in vitro clin-
7 ical test affected by such change that is
8 within the scope of the technology certifi-
9 cation order will meet the applicable stand-
10 ard; and

11 “(ii) be limited to such information
12 that is needed to support the change.

13 “(B) CONTENT.—Unless otherwise speci-
14 fied by the Secretary, a supplemental applica-
15 tion under this subsection shall include—

16 “(i) a description of the change, in-
17 cluding a rationale for implementing such
18 change;

19 “(ii) a description of how the change
20 was evaluated;

21 “(iii) data from a representative in
22 vitro clinical test or tests that supports a
23 showing that, in using the modified proce-
24 dure or procedures, all eligible in vitro clin-
25 ical tests within the scope of the tech-

1 nology certification will meet the applicable
2 standard;

3 “(iv) as applicable, information to
4 demonstrate that the modified procedure
5 or procedures submitted under subsection
6 (c)(2)(F) continue to conform to applicable
7 requirements under section 587K; and

8 “(v) any other information requested
9 by the Secretary.

10 “(3) CHANGES IN RESPONSE TO A PUBLIC
11 HEALTH RISK.—

12 “(A) IN GENERAL.—If the holder of a
13 technology certification makes a change to an
14 in vitro clinical test or tests to address a poten-
15 tial risk to public health by adding a new speci-
16 fication or test method, such holder may imme-
17 diately implement such change and shall submit
18 a notification for such change to the Secretary
19 within 30 days.

20 “(B) CONTENT.—Any notification to the
21 Secretary under this paragraph shall include—

22 “(i) a summary of the relevant
23 change;

24 “(ii) the rationale for implementing
25 such change;

1 “(iii)(I) if such a change necessitates
2 a change to the procedures reviewed as
3 part of the granted technology certification
4 order, the modified procedures; or

5 “(II) if the procedures were not
6 changed, an explanation as to why they
7 were not changed; and

8 “(iv) if such a change necessitates a
9 change to the procedures reviewed as part
10 of the granted technology certification
11 order, data from a representative in vitro
12 clinical test or tests that support a showing
13 that, in using the modified procedures, all
14 eligible in vitro clinical tests within the
15 scope of the technology certification will
16 meet the applicable standard.

17 “(f) TEMPORARY HOLD.—

18 “(1) IN GENERAL.—Subject to the process
19 specified in paragraph (2), and based on one or
20 more findings under paragraph (4), the Secretary
21 may issue a temporary hold prohibiting any holder
22 of a technology certification order issued under this
23 section from introducing into interstate commerce
24 an in vitro clinical test that was not previously the
25 subject of a listing under section 587J. The tem-

1 porary hold shall identify the grounds for the tem-
2 porary hold under paragraph (4) and the rationale
3 for such finding.

4 “(2) PROCESS FOR ISSUING A TEMPORARY
5 HOLD.—If the Secretary makes a finding that a
6 temporary hold may be warranted based on one or
7 more grounds specified in paragraph (4), the Sec-
8 retary shall promptly notify the holder of the tech-
9 nology certification order of such finding and pro-
10 vide 30 calendar days for the developer to come into
11 compliance with or otherwise resolve the finding.

12 “(3) WRITTEN REQUESTS.—Any written re-
13 quest to the Secretary from the holder of a tech-
14 nology certification order that a temporary hold
15 under paragraph (1) be removed shall receive a deci-
16 sion, in writing and specifying the reasons therefore,
17 within 90 days after receipt of such request. Any
18 such request shall include information to support the
19 removal of the temporary hold.

20 “(4) GROUNDS FOR TEMPORARY HOLD.—The
21 Secretary may initiate a temporary hold under this
22 subsection upon a finding that the holder of a tech-
23 nology certification order—

1 “(A) is not in compliance with the require-
2 ments of the technology certification order pur-
3 suant to subsection (b)(1)(D);

4 “(B) offers one or more in vitro clinical
5 tests with advertising or labeling that is false or
6 misleading;

7 “(C) has reported a correction or removal
8 of an in vitro clinical test that is offered under
9 a technology certification order under this sec-
10 tion and has failed to demonstrate that the
11 issue or issues causing the correction or re-
12 moval does not adversely impact the ability of
13 other in vitro clinical tests offered under the
14 same technology certification order to meet the
15 applicable standard; or

16 “(D) has introduced into interstate com-
17 merce an in vitro clinical test under a tech-
18 nology certification order and such test is adul-
19 terated or misbranded, based on a determina-
20 tion by the Secretary, and has failed to dem-
21 onstrate that the issue or issues causing the
22 adulteration or misbranding does not adversely
23 impact the ability of other in vitro clinical tests
24 offered under the same technology certification

1 granted under this section to meet the applica-
2 ble standard.

3 “(g) WITHDRAWAL.—The Secretary may, after due
4 notice and opportunity for an informal hearing, issue an
5 order withdrawing a technology certification order includ-
6 ing all tests introduced into interstate commerce under the
7 technology certification order if the Secretary finds that—

8 “(1) the application, supplement, or report
9 under subsection (h) contains false or misleading in-
10 formation or fails to reveal a material fact;

11 “(2) such holder fails to correct false or mis-
12 leading labeling or advertising upon the request of
13 the Secretary;

14 “(3) in connection with a technology certifi-
15 cation, the holder provides false or misleading infor-
16 mation to the Secretary; or

17 “(4) the holder of such technology certification
18 order fails to correct the grounds for a temporary
19 hold within a timeframe specified in the temporary
20 hold order.

21 “(h) REPORTS TO CONGRESS.—

22 “(1) IN GENERAL.—Not later than 1 year after
23 the effective date of the VALID Act of 2022, and
24 annually thereafter for the next 4 years, the Sec-
25 retary shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and
2 the Committee on Energy and Commerce of the
3 House of Representatives, and make publicly avail-
4 able, including through posting on the website of the
5 Food and Drug Administration, a report containing
6 the information described in paragraph (2).

7 “(2) CONTENT.—

8 “(A) IN GENERAL.—Each report under
9 paragraph (1) shall address, at a minimum—

10 “(i) the total number of applications
11 for technology certifications filed, granted,
12 withdrawn and denied;

13 “(ii) the total number of technology
14 certification orders the Secretary put on
15 temporary hold under subsection (h) and
16 the number of technology certification or-
17 ders withdrawn under subsection (i);

18 “(iii) the types of technologies for
19 which the Secretary granted technology
20 certification orders;

21 “(iv) the total number of holders of
22 technology certification orders that are in
23 effect; and

24 “(v) the total number of in vitro clin-
25 ical test categories that required premarket

1 review under section 587B that were reded-
2 igned as eligible in vitro clinical tests
3 under this section.

4 “(B) FINAL REPORT.—The fifth report
5 submitted under paragraph (1) shall include a
6 summary of, and responses to, comments raised
7 in the docket.

8 “(C) PERFORMANCE REPORTS.—The re-
9 ports required under this section may be issued
10 with performance reports as required under sec-
11 tion 829 of the VALID Act of 2022.

12 “(i) PUBLIC MEETING AND INPUT.—

13 “(1) PUBLIC DOCKET.—Not later than 30 days
14 after the date of enactment of the VALID Act of
15 2022, the Secretary shall establish a public docket to
16 receive comments concerning recommendations for
17 implementation of this section, including criteria and
18 procedures for subsections (c) through (h). The pub-
19 lic docket shall remain open for at least 1 year after
20 the establishment of the public docket.

21 “(2) PUBLIC MEETING.—Not later than 180
22 days after the date of enactment of the VALID Act
23 of 2022, the Secretary shall convene a public meet-
24 ing to which stakeholders from organizations rep-
25 resenting patients and consumers, academia, and the

1 in vitro clinical test industry are invited to discuss
2 the technology certification process including appli-
3 cation requirements, inspections, alignment with
4 third-party accreditors, and the definition of the
5 term ‘technology’ under section 587.

6 “(j) REGULATIONS.—The Secretary shall issue regu-
7 lations regarding the technology certification process, in-
8 cluding describing criteria or procedures relating to tech-
9 nology certification under this section, which shall be sub-
10 ject to public comment for a minimum of 60 days from
11 issuance prior to finalizing such regulations after consid-
12 ering the comments received. The regulation shall include
13 an outline of the application process, opportunities to meet
14 with officials of the Food and Drug Administration, and
15 plans to streamline inspections.

16 “(k) NOTIFICATION.—Notwithstanding subsection
17 (a)(1), a first-of-a-kind in vitro clinical test or a combina-
18 tion product that meets the definition of a moderate-risk
19 test under section 587A may be introduced into interstate
20 commerce under a technology certification order that has
21 been issued by the Secretary **【with an applicable tech-**
22 **nology/certified to introduce into interstate commerce**
23 **tests under an applicable technology】** upon notification
24 from the developer to the Secretary **【10/30/60】** days prior
25 to introducing such tests into interstate commerce. Such

1 notification from the developer shall include information
2 demonstrating that the test is moderate-risk and within
3 the scope of the applicable technology certification order.
4 The Secretary shall issue a notification to the developer
5 that such test may not be introduced into interstate com-
6 merce under such order if the Secretary determines that—

7 “(1) such test—

8 “(A) does not meet the definition of a
9 moderate-risk test under section 587A;

10 “(B) is not eligible to be introduced into
11 interstate commerce under the specific tech-
12 nology certification order issued by the Sec-
13 retary; or

14 “(C) is not eligible for technology certifi-
15 cation under subsection (b)(2); or

16 “(2) based on the information included in the
17 notification submitted by the developer pursuant to
18 this subsection, there is insufficient information for
19 the Secretary to make the determinations described
20 in subparagraphs (A), (B), and (C) of paragraph
21 (1).

22 **“SEC. 587E. MITIGATING MEASURES.**

23 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

24 “(1) ESTABLISHING, CHANGING, OR WITH-
25 DRAWING.—

1 “(A) ESTABLISHMENT.—The Secretary
2 may establish and require, on the basis of evi-
3 dence, mitigating measures for any in vitro clin-
4 ical test or category of in vitro clinical tests
5 with the same intended use that is introduced
6 or delivered for introduction into interstate
7 commerce after the establishment of such miti-
8 gating measures.

9 “(B) METHODS OF ESTABLISHMENT.—The
10 Secretary may establish mitigating measures—

11 “(i) under the process set forth in
12 subparagraph (D);

13 “(ii) as provided under section 587F;
14 or

15 “(iii) through a premarket approval or
16 technology certification order, which may
17 establish mitigating measures for an indi-
18 vidual in vitro clinical test or a category of
19 in vitro clinical tests.

20 “(C) METHODS OF CHANGE OR WITH-
21 DRAWAL.—The Secretary may change or with-
22 draw mitigating measures—

23 “(i) under the process set forth in
24 subparagraph (D); or

25 “(ii) as provided under section 587F.

1 “(D) PROCESS FOR ESTABLISHMENT,
2 CHANGE, OR WITHDRAWAL.—Notwithstanding
3 subchapter II of chapter 5 of title 5, United
4 States Code, the Secretary may, upon the ini-
5 tiative of the Secretary or upon petition of an
6 interested person—

7 “(i) establish, change, or withdraw
8 mitigating measures for an in vitro clinical
9 test or category of in vitro clinical tests
10 by—

11 “(I) publishing a proposed order
12 in the Federal Register;

13 “(II) providing an opportunity
14 for public comment for a period of not
15 less than 30 60 calendar days; and

16 “(III) after consideration of any
17 comments submitted, publishing a
18 final order in the Federal Register
19 that responds to the comments sub-
20 mitted, and which shall include a rea-
21 sonable transition period.

22 “(E) EFFECT OF MITIGATING MEASURES
23 ON GRANDFATHERED TESTS.—A mitigating
24 measure shall not be required by the Secretary
25 for an in vitro clinical test subject to section

1 587G(a), unless otherwise provided under sec-
2 tion 587F.

3 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
4 CLEARED OR EXEMPT AS DEVICES WITH SPECIAL
5 CONTROLS.—

6 “(A) IN GENERAL.—Any special controls
7 applicable to an in vitro clinical test previously
8 cleared or exempt under section 510(k), or clas-
9 sified under section 513(f)(2) prior to date of
10 enactment of the VALID Act of 2022, including
11 any such special controls established during the
12 period beginning on the date of enactment of
13 the VALID Act of 2022 and ending on the ef-
14 fective date of such Act (as described in section
15 5(b) of such Act)—

16 “(i) shall continue to apply to such in
17 vitro clinical test after such effective date;
18 and

19 “(ii) are deemed to be mitigating
20 measures as of the effective date specified
21 in section 825(a)(1)(A) of the VALID Act
22 of 2022.

23 “(B) CHANGES.—Notwithstanding sub-
24 paragraph (A), the Secretary may establish,
25 change, or withdraw mitigating measures for

1 such tests or category of tests using the proce-
2 dures under paragraph (1).

3 “(b) DOCUMENTATION.—

4 “(1) IN VITRO CLINICAL TESTS SUBJECT TO
5 PREMARKET REVIEW.—The developer of an in vitro
6 clinical test subject to premarket review under sec-
7 tion 587B and to which mitigating measures apply
8 shall—

9 “(A) in accordance with section
10 587B(c)(2)(G)(i), submit documentation to the
11 Secretary as part of the application for the test
12 under subsection (c) or (d) of section 587B
13 demonstrating that such mitigating measures
14 have been met;

15 “(B) if such application is approved, main-
16 tain documentation demonstrating that such
17 mitigating measures continue to be met fol-
18 lowing a test modification by the developer; and

19 “(C) make such documentation available to
20 the Secretary upon request or inspection.

21 “(2) OTHER TESTS.—The developer of an in
22 vitro clinical test that is offered under a technology
23 certification order or other exemption from pre-
24 market review under section 587B and to which
25 mitigating measures apply shall—

1 “(A) maintain documentation in accord-
2 ance with the applicable quality requirements
3 under section 587J demonstrating that such
4 mitigating measures continue to be met fol-
5 lowing a test modification by the developer;

6 “(B) make such documentation available to
7 the Secretary upon request or inspection; and

8 “(C) include in the performance summary
9 for such test a brief description of how such
10 mitigating measures are met, if applicable.

11 **“SEC. 587F. REGULATORY PATHWAY DESIGNATION.**

12 “(a) PATHWAY DETERMINATIONS.—

13 “(1) IN GENERAL.—After considering available
14 evidence with respect to an in vitro clinical test or
15 category of in vitro clinical tests with the same in-
16 tended use, including the identification, establish-
17 ment, and implementation of mitigating measures
18 under section 587E, as appropriate, the Secretary
19 may, upon the initiative of the Secretary or upon re-
20 quest of a developer, determine that—

21 “(A) such in vitro clinical test is high-risk
22 and subject to premarket review under section
23 587B;

24 “(B) such in vitro clinical tests, including
25 a first of a kind test, is eligible for abbreviated

1 premarket review under section 587B(d) or
2 technology certification under section
3 587D(b)(2); or

4 “(C) such in vitro clinical test, including a
5 first of a kind test is low-risk or otherwise ex-
6 empt from premarket review under section
7 587B.

8 “(2) REQUESTS.—

9 “(A) SUBMISSIONS BY DEVELOPERS.—

10 “(i) SPECIAL PREMARKET REVIEW;
11 TECHNOLOGY CERTIFICATION.—A devel-
12 oper submitting a request that the Sec-
13 retary make a determination as described
14 in paragraph (1)(B) shall submit informa-
15 tion that the in vitro clinical test is mod-
16 erate-risk or propose mitigating measures,
17 if applicable, that would support such a de-
18 termination.

19 “(ii) LOW-RISK; EXEMPT FROM PRE-
20 MARKET REVIEW.—A developer submitting
21 a request that the Secretary make a deter-
22 mination as described in paragraph (1)(C)
23 shall submit information that the in vitro
24 clinical test is low-risk, or propose miti-

1 “(v) Use of such technology, including
2 historical use.

3 “(vi) Multiple scientific publications
4 by different authors.

5 “(vii) Adoption by the scientific or
6 clinical community.

7 “(viii) Real world evidence.

8 “(B) Whether the criteria for performance
9 of the test are well-established to be sufficient
10 for the intended use.

11 “(C) The clinical circumstances under
12 which the in vitro clinical test is used, including
13 whether the in vitro clinical test is the sole de-
14 terminate for the diagnosis or treatment of the
15 targeted disease, and the availability of other
16 tests (such as confirmatory or adjunctive tests)
17 or relevant material standards.

18 “(D) Whether such mitigating measures
19 sufficiently mitigate the risk of harm such that
20 the test or category of tests is moderate-risk or
21 low-risk.

22 “(4) PROCESS.—

23 “(A) IN GENERAL.—Except as provided
24 under subparagraph (B), any action under
25 paragraph (1) shall be made by publication of

1 a notice of such proposed action on the website
2 of the Food and Drug Administration, the con-
3 sideration of comments to a public docket on
4 such proposal, and publication of a final action
5 on such website within 60 calendar days of the
6 close of the comment period posted to such pub-
7 lic docket, notwithstanding subchapter II of
8 chapter 5 of title 5, United States Code.

9 “(B) PROCESS FOR FIRST-OF-A-KIND
10 TEST.—In the case of an in vitro clinical test
11 that has not yet been approved under section
12 587B or offered under a technology certification
13 order issued under 587D and that the test de-
14 veloper or the Secretary believes may be a first-
15 of-a-kind test, any submission by the developer
16 and action by the Secretary shall not be subject
17 to publication or to a public comment period.
18 Such communications will be subject to the pro-
19 tections for confidential commercial information
20 and trade secrets, and the Secretary shall issue
21 its determination as to the classification of the
22 test within 60 days.

23 “(C) CONFIRMED FIRST-OF-A-KIND
24 TEST.—Pursuant to a classification decision of
25 the Secretary under subparagraph (B) with re-

1 gard to a test that is confirmed to be a first-
2 of-a-kind test, such test shall no longer be con-
3 sidered first of a kind for purposes of deter-
4 mining whether the test is eligible to submit an
5 abbreviated premarket application under section
6 587B(b) or a technology certification applica-
7 tion under section 587D.

8 “(D) EFFECT OF DETERMINATION.—A de-
9 termination by the Secretary under subpara-
10 graph (B) does not constitute approval under
11 section 587B or other form of marketing au-
12 thorization, and the Secretary shall publish the
13 classification of such test, to the extent it is
14 first-of-a-kind, upon the subsequent approval of
15 the test pursuant to section 587B, or the subse-
16 quent offering of the test pursuant to section
17 587D **【as a test described in or section**
18 **587(12)】**.

19 “(b) REDESIGNATION.—The Secretary may redesi-
20 gnate the risk category of an in vitro clinical test or tests
21 within the same intended use if new clinical information
22 indicates that the exemption of an in vitro clinical test
23 or tests from premarket review under section 587B or ex-
24 emption under section 587C has a reasonable probability
25 of resulting in severe adverse health consequences, includ-

1 ing the absence, significant delay, or discontinuation of
2 appropriate medical treatment.

3 “(c) TRANSITION PERIOD.—Upon a decision by the
4 Secretary to change a regulatory pathway designation, or
5 reclassifies an in vitro clinical test, or category of in vitro
6 clinical tests, the Secretary shall provide an appropriate
7 transition period with respect to any new requirements.

8 “(d) APPEALS.—A decision by the Secretary under
9 this section shall be deemed a significant decision subject
10 to appeal under section 587P.

11 “(e) ADVISORY COMMITTEE.—The Secretary may re-
12 quest recommendations from an advisory committee under
13 section 587H pursuant to carrying out this section.

14 “(f) REQUEST FOR INFORMAL FEEDBACK.—Before
15 submitting a premarket application or technology certifi-
16 cation application for an in vitro clinical test—

17 “(1) the developer of the test may submit to the
18 Secretary a written request for a meeting, con-
19 ference, or written feedback to discuss and provide
20 information relating to the regulation of such in
21 vitro clinical test which may include—

22 “(A) the submission process and the type
23 and amount of evidence expected to dem-
24 onstrate the applicable standard;

1 “(B) which regulatory pathway is appro-
2 priate for an in vitro clinical test; and

3 “(C) an investigation plan for an in vitro
4 clinical test, including a clinical protocol; and

5 “(2) upon receipt of such a request, the Sec-
6 retary shall—

7 “(A) if a meeting is requested—

8 “(i) within 60 calendar days after
9 such receipt, or within such time period as
10 may be agreed to by the developer, meet or
11 confer with the developer submitting the
12 request; and

13 “(ii) within 15 calendar days after
14 such meeting or conference, provide to the
15 developer a written record or response de-
16 scribing the issues discussed and conclu-
17 sions reached in the meeting or conference;
18 and

19 “(B) if written feedback is requested, pro-
20 vide feedback to the requestor within 75 days
21 after such receipt.

22 **“SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.**

23 “(a) IN GENERAL.—Subject to subsection (d), an in
24 vitro clinical test is exempt from premarket review under
25 587B, labeling requirements under 587L, and test design

1 requirements and quality requirements under 587K and
2 may be lawfully marketed subject to the other applicable
3 requirements of this Act, if the test—

4 “(1) was first offered for clinical use by **【a lab-**
5 **oratory】** before the date of enactment of the VALID
6 Act of 2022;

7 “(2) was developed by a clinical laboratory for
8 which a certificate was in effect under section 353
9 of the Public Health Service Act that meets the re-
10 quirements for performing tests of high complexity;
11 and

12 “(3) is performed—

13 “(A) in the same clinical laboratory in
14 which the test was developed for which a certifi-
15 cation is still in effect under section 353 of the
16 Public Health Service Act for which a certifi-
17 cation is still in effect for the performance of
18 tests of high complexity;

19 “(B) by another clinical laboratory for
20 which a certificate is in effect under section 353
21 of such Act **【that meets the requirements to**
22 **perform tests of high complexity】**, and that is
23 within the same corporate organization and
24 having common ownership by the same parent

1 corporation as the laboratory in which the test
2 was developed; or

3 “(C) **【**in the case of a test that was devel-
4 oped by the Centers for Disease Control and
5 Prevention or another laboratory a public
6 health laboratory network coordinated or man-
7 aged by the Centers for Disease Control and
8 Prevention,**】** by a clinical laboratory for which
9 a certificate is in effect under section 353 of
10 such Act that meets the requirements to per-
11 form tests of high complexity, and that is with-
12 in a public health laboratory network coordi-
13 nated or managed by the Centers for Disease
14 Control and Prevention;

15 “(4) does not have in effect an approval under
16 section 515, a clearance under section 510(k), an
17 authorization under section 513(f)(2), an exemption
18 under section 520(m), or a license under section 351
19 of the Public Health Service Act;

20 “(5) is not modified on or after the date of en-
21 actment of the VALID Act of 2022 by its initial de-
22 veloper (or another person) in a manner such that
23 the test does not conform with section 587C(a)(6);

24 **【**“(6) **【**the labeling accompanying**】** each test
25 **【**result that is in the form of a test report template

1 or ordering information] for the test bears a state-
2 ment that reads as follows: ‘This in vitro clinical test
3 has not been reviewed by the Food and Drug Ad-
4 ministration.’; and]

5 [“(7) the developer of the test—]

6 [“(A) maintains documentation dem-
7 onstrating that the test meets and continues to
8 meet the criteria set forth in this subsection;]

9 [“(B) makes such documentation available
10 to the Secretary upon request.]

11 “(b) MODIFICATIONS.—In the case of an in vitro clin-
12 ical test that meets the criteria specified in subsection (a),
13 such test continues to meet such criteria if the [test is
14 modified and the modification is not of a type described
15 in subsection (a)(5)], and the person modifying such in
16 vitro clinical test—

17 “(1) documents each such modification and
18 maintains documentation of the basis for such deter-
19 mination;

20 “(2) provides such documentation [relating to
21 the change] to the Secretary upon request or inspec-
22 tion; and

23 “(3) does not modify the in vitro clinical test
24 such that it no longer meets the criteria under sub-
25 section (a).

1 “(c) SPECIAL RULE.—

2 “(1) REVIEW APPLICABLE.—Notwithstanding
3 any other provision of this section, an in vitro clin-
4 ical test (including specimen receptacles) described
5 in subsection (a) shall be subject to the requirements
6 of section 587B if the Secretary determines, in ac-
7 cordance with paragraph (2)(D), that—

8 “(A) there is insufficient valid scientific
9 evidence to support determining that such in
10 vitro clinical test is analytically valid or clini-
11 cally valid;

12 “(B) such in vitro clinical test is being of-
13 fered by its developer with any deceptive or
14 fraudulent analytical or clinical claims;

15 “(C) it is probable that such in vitro clin-
16 ical test will cause serious adverse health con-
17 sequences; or

18 “(D) in the case of specimen receptacles,
19 there is sufficient evidence indicating that—

20 “(i) the specimen receptacle does not
21 perform as intended **[by the developer]**;

22 “(ii) does not support the analytical
23 validity of tests with which it is used; or

24 “(iii) as applicable, is not safe for use.

25 “(2) PROCESS.—

1 “(A) REQUEST FOR INFORMATION.—If the
2 Secretary makes a determination¹, based on
3 sufficient evidence,² that the criteria under
4 paragraph (1) may apply to an in vitro clinical
5 test and provides, in writing, the basis for such
6 determination to the developer, the Secretary
7 may request that the developer of the test sub-
8 mit information—

9 “(i) pertaining to such criteria; and

10 “(ii) establishing the basis for any
11 claimed exemption from premarket review.

12 “(B) DEADLINE FOR SUBMITTING INFOR-
13 MATION.—Upon receiving a request for infor-
14 mation under subparagraph (A), the developer
15 of an in vitro clinical test shall submit the in-
16 formation requested pursuant to subparagraph
17 (A) within 30 days of receipt of such request.

18 “(C) REVIEW DEADLINE.—Upon receiving
19 a submission under subparagraph (B), the Sec-
20 retary shall—

21 “(i) review the submitted information
22 within 60 calendar days of such receipt;
23 and

1 “(ii) determine whether the criteria
2 listed in paragraph (1) apply to the in
3 vitro clinical test.

4 “(D) PREMARKET REVIEW REQUIRED.—

5 “(i) IN GENERAL.—If the Secretary
6 finds that the criteria listed in paragraph
7 (1) apply to the in vitro clinical test and
8 communicates such determination in writ-
9 ing to the developer, the developer shall—

10 “(I) promptly, and not later than
11 90 days after the date of receipt of
12 such notification, submit an applica-
13 tion for premarket review under sec-
14 tion 587B or for technology certifi-
15 cation under section 587D; or

16 “(II) cease to market the test.

17 “(ii) EXTENSION.—The Secretary
18 may grant an extension to a developer of
19 the 90-day time period under clause (i)(II),
20 as appropriate.

21 “(E) CONTINUED MARKETING.—During
22 the period beginning on the date of a request
23 for information under subparagraph (B) and
24 ending on the date of the disposition of an ap-
25 plication for premarket review of the in vitro

1 clinical test under section 587B or an applica-
2 tion for technology certification for the in vitro
3 clinical test under section 587D, the developer
4 of the test may continue to offer the in vitro
5 clinical test, unless the Secretary issues an
6 order to the developer under subparagraph (G)
7 to immediately cease distribution of such test.

8 “(F) REVOCATION OF EXEMPTION.—Sub-
9 ject to the extension period under subparagraph
10 (D)(ii) and notwithstanding subsection (a), if
11 the Secretary finds that the criteria listed in
12 paragraph (1) apply to the in vitro clinical test,
13 such test is no longer exempt from premarket
14 review under 587B, labeling requirements under
15 587L, or test design requirements and quality
16 requirements under 587K.

17 “(G) ORDER TO CEASE DISTRIBUTION.—

18 “(i) IN GENERAL.—If the developer of
19 an in vitro clinical test fails to submit an
20 application for the test by the deadline ap-
21 plicable under subparagraph (D), or the
22 Secretary finds that the criteria listed in
23 paragraph (1) apply to an in vitro clinical
24 test and that it is in the best interest of
25 the public health, the Secretary may issue

1 an order, within 10 calendar days of the
2 applicable deadline or finding by the Sec-
3 retary, requiring the developer of such in
4 vitro clinical test, and any other appro-
5 priate person (including a distributor or
6 retailer of the in vitro clinical test) to im-
7 mediately—

8 “(I) cease distribution of the test
9 pending approval of an application for
10 premarket review of the in vitro clin-
11 ical test under section 587B or tech-
12 nology certificate under section 587D;
13 and

14 “(II) notify health professionals
15 and other user facilities of the order
16 to cease distribution and, where ap-
17 propriate, advise health care profes-
18 sionals to cease use of such test.

19 “(ii) HEARING AND REVIEW.—An
20 order under clause (i) shall provide the
21 person subject to the order with an oppor-
22 tunity for an informal hearing, to be held
23 not later than 10 days after the date of the
24 issuance of the order, on the actions re-
25 quired by the order and on whether the

1 order should be amended to require a re-
2 call of such in vitro clinical test. If, after
3 providing an opportunity for such a hear-
4 ing, the Secretary determines that inad-
5 equate grounds exist to support the actions
6 required by the order, the Secretary shall
7 terminate the order within 30 days of the
8 hearing. Upon terminating an order, the
9 Secretary shall provide written notice of
10 such termination to the developer.

11 “(H) AMENDMENT TO REQUIRE RECALL.—
12 If the Secretary determines that an order
13 issued under subparagraph (F) should be
14 amended to include a recall of the in vitro clin-
15 ical test with respect to which the order was
16 issued, the Secretary shall amend the order to
17 require a recall. In such amended order, the
18 Secretary shall specify a timeframe in which the
19 in vitro clinical test recall will occur and shall
20 otherwise proceed in accordance with section
21 587N.

22 “(I) EFFECT OF TEST APPROVAL.—Any
23 order issued under this subparagraph with re-
24 spect to an in vitro clinical test shall cease to
25 be in effect if such test is granted approval

1 under section 587B or subject to a technology
2 certificate under section 587D, provided that
3 the in vitro clinical test is developed and offered
4 for clinical use in accordance with such ap-
5 proval or order.

6 **“SEC. 587H. ADVISORY COMMITTEES.**

7 “(a) IN GENERAL.—The Secretary may establish ad-
8 visory committees or use advisory committee panels of ex-
9 perts established before the date of enactment of the
10 VALID Act of 2022 [(including a device classification
11 panel under section 513)] for the purposes of providing
12 expert scientific advice and making recommendations re-
13 lated to—

14 “(1) the approval of an application for an in
15 vitro clinical test submitted under this subchapter,
16 including for evaluating, as applicable, the analytical
17 validity, clinical validity, and safety of in vitro clin-
18 ical tests;

19 “(2) the potential effectiveness of mitigating
20 measures for a determination [on the applicable reg-
21 ulatory pathway under section 587F(b)] or risk
22 evaluation for an in vitro clinical test or tests;

23 “(3) quality requirements under section 587K
24 or applying such requirements to in vitro clinical
25 tests developed or imported by developers;

1 “(4) appeals under section 587P; or

2 “(5) such other purposes as the Secretary de-
3 termines appropriate.

4 “(b) APPOINTMENTS.—

5 “(1) VOTING MEMBERS.—The Secretary shall
6 appoint to each committee established under sub-
7 section (a), as voting members, individuals who are
8 qualified by training and experience to evaluate in
9 vitro clinical tests referred to the committee for the
10 purposes specified in subsection (a), including indi-
11 viduals with, to the extent feasible, scientific exper-
12 tise in the development, manufacture, or utilization
13 of such in vitro clinical tests, laboratory operations,
14 and the use of in vitro clinical tests. The Secretary
15 shall designate one member of each committee to
16 serve as chair.

17 “(2) NONVOTING MEMBERS.—In addition to the
18 individuals appointed pursuant to paragraph (1), the
19 Secretary shall appoint to each committee estab-
20 lished under subsection (a), as nonvoting members—

21 “(A) a representative of consumer inter-
22 ests; and

23 “(B) a representative of interests of in
24 vitro clinical test developers not directly af-

1 fected by the matter to be brought before the
2 committee.

3 “(3) LIMITATION.—No individual who is a reg-
4 ular full-time employee of the United States and en-
5 gaged in the administration of this Act may be a
6 member of any advisory committee established under
7 subsection (a).

8 “(4) EDUCATION AND TRAINING.—The Sec-
9 retary shall, as appropriate, provide education and
10 training to each new committee member before such
11 member participates in a committee’s activities, in-
12 cluding education regarding requirements under this
13 Act and related regulations of the Secretary, and the
14 administrative processes and procedures related to
15 committee meetings.

16 “(5) MEETINGS.—The Secretary shall ensure
17 that scientific advisory committees meet regularly
18 and at appropriate intervals so that any matter to
19 be reviewed by such a committee can be presented
20 to the committee not more than 60 calendar days
21 after the matter is ready for such review. Meetings
22 of the committee may be held using electronic or tel-
23 ephonic communication to convene the meetings.

24 “(6) COMPENSATION.—Members of an advisory
25 committee established under subsection (a), while at-

1 tending meetings or conferences or otherwise en-
2 gaged in the business of the advisory committee—

3 “(A) shall be entitled to receive compensa-
4 tion at rates to be fixed by the Secretary, but
5 not to exceed the daily equivalent of the rate in
6 effect for positions classified above level GS–15
7 of the General Schedule; and

8 “(B) may be allowed travel expenses as au-
9 thorized by section 5703 of title 5, United
10 States Code, for employees serving intermit-
11 tently in the Government service.

12 “(c) GUIDANCE.—The Secretary may issue guidance
13 on the policies and procedures governing advisory commit-
14 tees established under subsection (a).

15 **“SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

16 “(a) IN GENERAL.—The purpose of this section is
17 to encourage the Secretary, and provide the Secretary with
18 sufficient authority, to apply efficient and flexible ap-
19 proaches to expedite the development of, and prioritize the
20 review of, in vitro clinical tests that represent break-
21 through technologies.

22 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
23 shall establish a program to expedite the development of,
24 and provide for the priority review of, in vitro clinical
25 tests.

1 “(c) ELIGIBILITY.—The program developed under
2 subsection (b) shall be available for any in vitro clinical
3 test that—

4 “(1) provides or enables more effective treat-
5 ment or diagnosis of life-threatening or irreversibly
6 debilitating human disease or conditions compared
7 to existing approved or cleared alternatives, includ-
8 ing an in vitro clinical test offered under a tech-
9 nology certification order; and

10 “(2) is a test—

11 “(A) that represents a breakthrough tech-
12 nology;

13 “(B) for which no approved or cleared al-
14 ternative in vitro clinical test exists, including
15 no in vitro clinical test offered under a tech-
16 nology certification order;

17 “(C) that offers a clinically meaningful ad-
18 vantage over any existing alternative in vitro
19 clinical test that is approved or cleared (includ-
20 ing any in vitro clinical test offered under a
21 technology certification order), including the po-
22 tential to reduce or eliminate the need for hos-
23 pitalization, improve patient quality of life, fa-
24 cilitate patients’ ability to manage their own
25 care (such as through self-directed personal as-

1 sistance), or establish long-term clinical effi-
2 ciencies; or

3 “(D) the availability of which is in the best
4 interest of patients or public health.

5 “(d) DESIGNATION.—

6 “(1) REQUEST.—To receive breakthrough des-
7 ignation under this section, an applicant may re-
8 quest that the Secretary designate the in vitro clin-
9 ical test for expedited development and priority re-
10 view. Any such request for designation may be made
11 at any time prior to, or at the time of, the submis-
12 sion of an application under section 587B or 587D,
13 and shall include information demonstrating that the
14 test meets the criteria described in subsection (c).

15 “(2) DETERMINATION.—Not later than 60 cal-
16 endar days after the receipt of a request under para-
17 graph (1), the Secretary shall determine whether the
18 in vitro clinical test that is the subject of the request
19 meets the criteria described in subsection (c). If the
20 Secretary determines that the test meets the criteria,
21 the Secretary shall designate the test for expedited
22 development and priority review.

23 “(3) REVIEW.—Review of a request under para-
24 graph (1) shall be undertaken by a team that is

1 composed of experienced staff and senior managers
2 of the Food and Drug Administration.

3 “(4) WITHDRAWAL.—

4 “(A) IN GENERAL.—The designation of an
5 in vitro clinical test under this subsection is
6 deemed to be withdrawn, and such in vitro clin-
7 ical test shall no longer be eligible for designa-
8 tion under this section, if an application for ap-
9 proval for such test under section 587B or
10 587D is denied. Such test shall be eligible for
11 breakthrough designation upon a new request
12 for such designation.

13 “(B) EXCEPTION.—The Secretary may not
14 withdraw a designation granted under this sub-
15 section based on the subsequent approval or
16 technology certification of another in vitro clin-
17 ical test that—

18 “(i) is designated under this section;

19 or

20 “(ii) was given priority review under
21 section 515B.

22 “(e) ACTIONS.—For purposes of expediting the devel-
23 opment and review of in vitro clinical tests under this sec-
24 tion, the Secretary may take the actions and additional
25 actions set forth in paragraphs (1) and (2), respectively,

1 of section 515B(e) when reviewing such tests. Any ref-
2 erence or authorization in section 515B(e) with respect
3 to a device shall be deemed a reference or authorization
4 with respect to an in vitro clinical test for purposes of this
5 section.

6 “(f) REGULATION AND GUIDANCE.—Not later than
7 the date specified for final regulations and guidance under
8 section 825 of the VALID Act of 2022, the Secretary shall
9 issue final regulation and guidance, as applicable on the
10 implementation of this section, as follows:

11 “(1) Such guidance shall—

12 “(A) set forth the process by which a per-
13 son may seek a designation under subsection
14 (d); and

15 “(B) provide a template for request under
16 subsection (d).

17 “(2) Such regulations shall—

18 “(A) identify the criteria the Secretary will
19 use in evaluating a request for designation; and

20 “(B) identify the criteria and processes the
21 Secretary will use to assign a team of staff, in-
22 cluding team leaders, to review in vitro clinical
23 tests designated for expedited development and
24 priority review, including any training required

1 for such personnel to ensure effective and effi-
2 cient review.

3 “(g) RULES OF CONSTRUCTION.—Nothing in this
4 section shall be construed to affect—

5 “(1) the criteria and standards for evaluating
6 an application pursuant to section 587B or 587D,
7 including the recognition of valid scientific evidence
8 as described in section 587(17) and consideration
9 and application of the least burdensome means de-
10 scribed under section 587BB(c);

11 “(2) the authority of the Secretary with respect
12 to clinical holds under section 587R;

13 “(3) the authority of the Secretary to act on an
14 application pursuant to section 587B before comple-
15 tion of an establishment inspection, as the Secretary
16 determines appropriate; or

17 “(4) the authority of the Secretary with respect
18 to postmarket surveillance under sections 587L(d)
19 and 587Y.

20 **“SEC. 587J. REGISTRATION AND LISTING.**

21 “(a) REGISTRATION REQUIREMENT.—

22 “(1) IN GENERAL.—Each person described in
23 subsection (b)(1) shall—

24 “(A) during the period beginning on Octo-
25 ber 1 and ending on December 31 of each year,

1 register with the Secretary the name of such
2 person, places of business of such person, all es-
3 tablishments engaged in the activities specified
4 under this paragraph, the establishment reg-
5 istration number of each such establishment,
6 and a point of contact for each such establish-
7 ment, including an electronic point of contact;
8 and

9 “(B) submit an initial registration con-
10 taining the information required under subpara-
11 graph (A) not later than—

12 “(i) the effective date of this section if
13 such establishment is engaged in any activ-
14 ity described in subsection (b)(1) on such
15 effective date, unless the Secretary estab-
16 lishes by guidance a date later than such
17 implementation date for all or a category
18 of such establishments; or

19 “(ii) 30 days prior to engaging in any
20 activity described in subsection (b)(1), if
21 such establishment is not engaged in any
22 activity described in this paragraph on
23 such effective date.

24 “(2) REGISTRATION NUMBERS.—The Secretary
25 may assign a registration number to any person or

1 an establishment registration number to any estab-
2 lishment registered in accordance with this section.
3 Registration information shall be made publicly
4 available by publication on the website maintained
5 by the Food and Drug Administration, in accord-
6 ance with subsection (d).

7 “(3) INSPECTION.—Each person or establish-
8 ment that is required to be registered with the Sec-
9 retary under this section shall be subject to inspec-
10 tion pursuant to section 704.

11 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL
12 TESTS.—

13 “(1) IN GENERAL.—Each person who—

14 “(A) is a developer; and

15 “(B) introduces or proposes to begin the
16 introduction or delivery for introduction into
17 interstate commerce through an exemption
18 under subsection (a)(1), (a)(2), (a)(3), or (g) of
19 section 587C or section 587G or through the
20 filing of an application under section 587B or
21 section 587D,

22 shall submit a listing to the Secretary containing the
23 information described in paragraph (2), (4), or (5),
24 as applicable, in accordance with the applicable
25 schedule described under subsection (c). Such listing

1 shall be prepared in such form and manner as the
2 Secretary may specify in guidance. Listing informa-
3 tion shall be submitted through the comprehensive
4 test information system in accordance with section
5 587U, as appropriate.

6 “(2) SUBMISSIONS.—Each developer submitting
7 a listing under paragraph (1) shall electronically
8 submit to the comprehensive test information system
9 described in section 587U the following information,
10 as applicable, for each in vitro clinical test for which
11 such person is a developer in the form and manner
12 prescribed by the Secretary, taking into account
13 least burdensome principles:

14 “(A) Name of the establishment and its es-
15 tablishment registration number.

16 “(B) Contact information for the official
17 correspondent for the listing.

18 “(C) Name (common name and trade
19 name, if applicable) of the in vitro clinical test
20 and its test listing number (when available).

21 “(D) The certificate number for any lab-
22 oratory certified by the Secretary under section
23 353 of the Public Health Service Act that
24 meets the requirements to perform high-com-
25 plexity testing and that is the developer of the

1 in vitro clinical test, and the certificate number
2 under such section for any laboratory that is
3 performing the test, is within the same cor-
4 porate organization, and has common ownership
5 by the same parent corporation.

6 “(E) Whether the in vitro clinical test is,
7 as applicable, offered as a test approved under
8 section 587B, cleared to be offered under a
9 granted technology certification order, or of-
10 fered as an exempt in vitro clinical test under
11 section 587A.

12 “(F) Indications for use information under
13 section 587(10).

14 “(G) Any substances detected by the in
15 vitro clinical test, such as an analyte, protein,
16 or pathogen.

17 “(H) Type or types of specimen or sample.

18 “(I) Test method.

19 “(J) Test purpose or purposes, as de-
20 scribed in section 201(ss)(2).

21 “(K) Diseases or conditions for which the
22 in vitro clinical test is intended for use.

23 “(L) Intended patient populations.

1 “(M) Context of use, such as in a clinical
2 laboratory, in a health care facility, prescription
3 home use, or without a prescription.

4 “(N) A brief summary of the analytical
5 and clinical performance of the in vitro clinical
6 test, and as applicable, the lot release criteria.

7 “(O) A brief description of conformance
8 with any applicable mitigating measures, re-
9 strictions, and standards.

10 “(P) Representative labeling for the in
11 vitro clinical test, as appropriate.

12 “(3) TEST LISTING NUMBER.—The Secretary
13 may assign a test listing number to each in vitro
14 clinical test that is the subject of a listing under this
15 section. The process for assigning test listing num-
16 bers may be established through guidance, and may
17 include the recognition of standards, formats, or
18 conventions developed by a third-party organization.

19 “(4) ABBREVIATED LISTING.—A person who is
20 not a developer but is otherwise required to register
21 pursuant to subsection (a) shall submit an abbrev-
22 viated listing to the Secretary containing the infor-
23 mation described in subparagraphs (A) through (C)
24 of paragraph (2), and the name of the developer.
25 The information shall be submitted in accordance

1 with the applicable schedule described under sub-
2 section (c). Such abbreviated listing shall be pre-
3 pared in such form and manner as the Secretary
4 may specify through guidance. Listing information
5 shall be submitted to the comprehensive test infor-
6 mation system in accordance with section 587U, as
7 appropriate.

8 “(5) GRANDFATHERED TESTS.—A developer of-
9 fering a test that is a grandfathered test under sec-
10 tion 587G(a) shall submit listing information re-
11 quired under subparagraphs (A) through (M) of
12 paragraph (2).

13 “(6) TESTS OFFERED UNDER A TECHNOLOGY
14 CERTIFICATION ORDER.—The holder of a technology
15 certification order under section 587D shall submit
16 additional listing information related to any changes
17 not otherwise submitted in a supplement under sub-
18 section 587D(f). Such information shall—

19 “(A) identify any changes that have been
20 made to the procedures in the technology cer-
21 tification order; and

22 “(B) identify the listings under section
23 587J for any new in vitro clinical test offered
24 under a technology certification order in the
25 preceding year.

1 “(7) EXEMPT TESTS.—A developer of an in
2 vitro clinical test who introduces or proposes to
3 begin the introduction or delivery for introduction
4 into interstate commerce that is otherwise exempt
5 from the requirement to submit listing information
6 pursuant to an exemption under section 587C may
7 submit listing information under this subsection.

8 “(c) TIMELINES FOR SUBMISSION OF LISTING IN-
9 FORMATION.—

10 “(1) IN GENERAL.—The timelines for submis-
11 sion of registration and listing under subsections (a)
12 and (b) are as follows:

13 “(A) For an in vitro clinical test that was
14 listed as a device under section 510(j) prior to
15 the effective date of this section, a person shall
16 maintain a device listing under section 510
17 until such time as the system for submitting
18 the listing information required under sub-
19 section (b) becomes available and thereafter
20 shall submit the listing information not later
21 than the later of 1 year after the system for
22 submitting the listing under this section be-
23 comes available or the effective date of this sec-
24 tion.

1 “(B) For an in vitro clinical test that is
2 subject to grandfathering under section
3 587G(a) a person shall submit the listing infor-
4 mation required under subsection (b)(5) not
5 later than the later of 1 year after the system
6 for submitting the listing under this section be-
7 comes available or the effective date of this sec-
8 tion.

9 “(C) For an in vitro clinical test that is
10 not described in subparagraph (A) or (B), a
11 person shall submit the required listing infor-
12 mation as follows:

13 “(i) For an in vitro clinical test that
14 is not exempt from premarket approval
15 under section 587B, a person shall submit
16 the required listing information, prior to
17 offering the in vitro clinical test and not
18 later than 30 business days after the date
19 of approval of the premarket approval ap-
20 plication.

21 “(ii) For an in vitro clinical test that
22 is exempt from premarket review under
23 section 587C, the required listing informa-
24 tion shall be submitted prior to offering
25 the in vitro clinical test.

1 “(D) The holder of a technology certifi-
2 cation order issued under section 587D shall
3 submit the information required under sub-
4 section (b)(6) each year at the time the devel-
5 oper submits an update in accordance with
6 paragraph (2)(B).

7 “(2) UPDATES.—

8 “(A) UPDATES AFTER CHANGES.—Each
9 developer required to submit listing information
10 under this section shall update such informa-
11 tion within 10 business days of any change that
12 causes any previously listed information to be
13 inaccurate or incomplete.

14 “(B) ANNUAL UPDATES.—Each developer
15 required to submit listing information under
16 this section shall update its information annu-
17 ally during the period beginning on October 1
18 and ending on December 31 of each year.

19 “(d) PUBLIC AVAILABILITY OF LISTING INFORMA-
20 TION.—

21 “(1) IN GENERAL.—Listing information sub-
22 mitted pursuant to this section shall be made pub-
23 licly available on the website of the Food and Drug
24 Administration in accordance with paragraph (3).

1 “(2) CONFIDENTIALITY.—Listing information
2 for an in vitro clinical test that is subject to pre-
3 market approval or technical certification shall re-
4 main confidential until such date as the in vitro clin-
5 ical test receives the applicable premarket approval
6 or the developer receives a technology certification
7 order and for subsequent tests introduced under a
8 technology certification order until their introduc-
9 tion.

10 “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY
11 REQUIREMENTS.—The public listing requirements of
12 this subsection shall not apply to any registration
13 and listing information submitted under subsection
14 (a) or (b), if the Secretary determines that such in-
15 formation—

16 “(A) is a trade secret or confidential com-
17 mercial information; or

18 “(B) if posted, would present a risk to na-
19 tional security.

20 “(e) SUBMISSION OF INFORMATION BY ACCREDITED
21 PERSONS.—If agreed upon by the developer, the informa-
22 tion required under this section may be submitted by a
23 person accredited under section 587Q.

24 **“SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.**

25 “(a) APPLICABILITY.—

1 “(1) IN GENERAL.—Each developer and each
2 other person required to register under section
3 587I(b)(1) shall establish and maintain quality re-
4 quirements in accordance with the applicable re-
5 quirements set forth in subsection (b).

6 “(2) CERTIFIED LABORATORY REQUIRE-
7 MENTS.—A developer shall establish and maintain
8 quality requirement under subsection (b)(2) if such
9 developer is a clinical laboratory certified by the Sec-
10 retary under section 353 of the Public Health Serv-
11 ice Act that—

12 “(A) is certified to perform high-com-
13 plexity testing;

14 “(B) develops an in vitro clinical test that
15 is for use only—

16 “(i) within the laboratory certified by
17 the Secretary under such section 353 in
18 which such test was developed; or

19 “(ii) within another laboratory cer-
20 tified by the Secretary under such section
21 353 if such laboratory is—

22 “(I) within the same corporate
23 organization and has common owner-
24 ship by the same parent corporation

1 as the laboratory in which the test
2 was developed; or

3 “(II) within a public health lab-
4 oratory network coordinated or man-
5 aged by the Centers for Disease Con-
6 trol and Prevention, if the test is de-
7 veloped by a public health laboratory
8 or the Centers for Disease Control
9 and Prevention; and

10 “(C) does not manufacture, produce, or
11 distribute in vitro clinical tests other than lab-
12 oratory test protocols.

13 “(3) REGULATIONS.—The Secretary shall pro-
14 mulgate quality system regulations implementing
15 this section. In promulgating such regulations under
16 this section, the Secretary shall consider whether,
17 and to what extent, international harmonization is
18 appropriate.

19 “(4) QUALITY SYSTEMS FOR HYBRID DEVEL-
20 OPERS OF BOTH LABORATORY TEST PROTOCOLS AND
21 FINISHED PRODUCTS.—An entity that develops both
22 finished products and laboratory test protocols shall
23 comply with subsection (b)(1) for activities related to
24 the development of any finished product and with

1 subsection (b)(2) for activities related to the develop-
2 ment of any laboratory test protocol.

3 “(b) QUALITY REQUIREMENTS.—

4 “(1) IN GENERAL.—The quality requirements
5 applicable under this section shall—

6 “(A) avoid duplication of regulations under
7 section 353 of the Public Health Service Act;

8 “(B) except as set forth in subsection
9 (a)(5), apply to developers of finished products,
10 related to the design and associated manufac-
11 ture and distribution of an in vitro clinical test
12 offered under this Act; and

13 “(C) shall include the following, as applica-
14 ble, subject to subparagraph (D) and para-
15 graphs (2) and (3)—

16 “(i) management responsibilities;

17 “(ii) quality audits;

18 “(iii) personnel;

19 “(iv) design controls;

20 “(v) document controls;

21 “(vi) purchasing controls;

22 “(vii) identification and traceability;

23 “(viii) production and process con-
24 trols;

25 “(ix) acceptance activities;

- 1 “(x) nonconforming in vitro clinical
2 tests;
3 “(xi) corrective and preventive action;
4 “(xii) labeling and packaging controls;
5 “(xiii) handling, storage, distribution,
6 and installation;
7 “(xiv) complaints and records;
8 “(xv) servicing; and
9 “(xvi) statistical techniques.

10 “(2) QUALITY REQUIREMENTS FOR LABORA-
11 TORY TEST PROTOCOLS.—Quality requirements ap-
12 plicable to the in vitro clinical tests and developers
13 described in subsections (a)(2) and (a)(5), as appli-
14 cable, shall—

15 “(A) avoid duplication of regulations for
16 performing laboratory examinations and other
17 procedures under section 353 of the Public
18 Health Service Act; and

19 “(B) not apply to laboratory operations.

20 “(3) EXCEPTION FOR LABORATORY TEST PRO-
21 Tocols.—Developers that are developing test proto-
22 cols for use as described in subsection (a)(2)(A) are
23 exempt from the requirements under paragraph
24 (1)(C) except for the requirements described in

1 clauses (iv), (vi), (ix), (xi), and (xiv) of such para-
2 graph.

3 “(4) QUALITY REQUIREMENTS FOR CERTAIN
4 LABORATORIES DISTRIBUTING IN VITRO CLINICAL
5 TESTS OR LABORATORY TEST PROTOCOLS WITHIN
6 ORGANIZATIONS OR PUBLIC HEALTH NETWORKS.—

7 “(A) IN GENERAL.—Quality requirements
8 applicable to the developer who is distributing
9 an in vitro clinical test or laboratory test pro-
10 tocol distributed as described in subparagraph
11 (B) shall consist of the following:

12 “(i) The requirements in paragraph
13 (2).

14 “(ii) The labeling requirements in
15 paragraph (1)(C)(xii).

16 “(iii) The requirement to maintain
17 records of the laboratories to which the
18 laboratory test protocol is distributed.

19 “(B) DISTRIBUTING LABORATORY.—Sub-
20 paragraph (A) shall apply to developers that
21 meet the following conditions:

22 “(i) The laboratory distributing the
23 test protocol is certified by the Secretary
24 under section 353 of the Public Health

1 Service Act and meets the requirements for
2 performing high-complexity testing.

3 “(ii) The laboratory develops its own
4 in vitro clinical test or modifies another de-
5 veloper’s in vitro clinical test in a manner
6 described in section 587C(a)(6).

7 “(iii) The laboratory distributes the
8 laboratory test protocol for such test only
9 to another laboratory that—

10 “(I) is certified by the Secretary
11 under section 353 of the Public
12 Health Service Act and meets the re-
13 quirements for performing the com-
14 plexity of the test being distributed to
15 the laboratory;

16 “(II)(aa) is within the same busi-
17 ness organization and having common
18 ownership with the developing labora-
19 tory; or

20 “(bb) as applicable, is a labora-
21 tory within a public health laboratory
22 network coordinated or managed by
23 the Centers for Disease Control and
24 Prevention; and

1 “(III) the developer intends to
2 have implement the protocol without
3 further modification.

4 “(c) REGULATIONS.—In implementing quality re-
5 quirements for test developers that participate in inter-
6 national audit programs under this section, the Secretary
7 shall—

8 “(1) for purposes of facilitating international
9 harmonization, consider whether the developer par-
10 ticipates in an audit program in which the United
11 States participates and recognizes compliance with,
12 or conformance to, such standards recognized by the
13 Secretary; and

14 “(2) ensure a least burdensome approach de-
15 scribed in section 587BB(c) by leveraging, to the ex-
16 tent applicable, the quality assurance requirements
17 applicable to developers certified by the Secretary
18 under section 353 of the Public Health Service Act.

19 **“SEC. 587L. LABELING REQUIREMENTS.**

20 “(a) IN GENERAL.—An in vitro clinical test shall
21 bear or be accompanied by labeling, as applicable, that
22 meets the requirements set forth in subsections (b) and
23 (c), unless such test is exempt under subsection (d) or (e).

24 “(b) LABELS.—

1 “(1) IN GENERAL.—The label of an in vitro
2 clinical test, shall meet the requirements set forth in
3 paragraph (2) if there is an immediate container to
4 which the label is applied.

5 “(2) REGULATIONS.—The label of an in vitro
6 clinical test shall state the name and place of busi-
7 ness of its developer and meet the requirements set
8 forth in regulations promulgated in accordance with
9 this section.

10 “(c) LABELING.—

11 “(1) IN GENERAL.—Labeling of an in vitro clin-
12 ical test, including labeling in the form of a package
13 insert, website, standalone laboratory reference docu-
14 ment, or other similar document, except the labeling
15 specified in paragraph (2), shall include—

16 “(A) adequate directions for use and shall
17 meet the requirements set forth in regulations
18 promulgated under this section, except as pro-
19 vided in subsection (d) or (e); and

20 “(B) the information described in para-
21 graph (2), as applicable.

22 “(2) CONTENT.—Labeling of an in vitro clinical
23 test shall include—

24 “(A) the test listing number that was pro-
25 vided to the developer at the time of listing;

1 “(B) information to facilitate reporting an
2 adverse event;

3 “(C) information regarding accessing the
4 performance summary data displayed in the
5 listing database for the test;

6 “(D) the intended use of the in vitro clin-
7 ical test; and

8 “(E) any warnings, contraindications, or
9 limitations.

10 “(3) PUBLIC AVAILABILITY OF INFORMATION.—

11 The Secretary shall make all of the information de-
12 scribed in paragraph (2) with respect to each in
13 vitro clinical test available to the public, as applica-
14 ble, in accordance with section 587U, except to the
15 extent that the Secretary determines that such infor-
16 mation—

17 “(A) is trade secret or confidential com-
18 mercial information; or

19 “(B) if posted, would present a risk to na-
20 tional security.

21 “(4) ADDITIONAL REQUIREMENTS.—Labeling
22 for an in vitro clinical test used for
23 immunoematology testing shall meet the applicable
24 requirements set forth in part 660 of title 21, Code
25 of Federal Regulations (or any successor regula-

1 tions), related to the labeling of blood grouping re-
2 agents, reagent red blood cells, and anti-human
3 globulin.

4 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
5 MENTS.—

6 “(1) IN GENERAL.—

7 “(A) IN GENERAL.—With respect to an in
8 vitro clinical test that meets the criteria of sub-
9 paragraph (B), the ‘state in one place’ regula-
10 tions under section 809.10(b) of title 21, Code
11 of Federal Regulations (or any successor regu-
12 lations) may be satisfied by the laboratory post-
13 ing such information on its website or in mul-
14 tiple documents, if such documents are main-
15 tained and accessible in one place.

16 “(B) APPLICABLE TESTS.—An in vitro
17 clinical test meets the criteria of this subpara-
18 graph if such test is—

19 “(i) developed by a laboratory cer-
20 tified by the Secretary under section 353
21 of the Public Health Service Act that
22 meets the requirements to perform tests of
23 high-complexity; and

24 “(ii) performed in—

1 “(I) the same laboratory in which
2 such test was developed; or

3 “(II) by another laboratory cer-
4 tified by the Secretary under section
5 353 of the Public Health Service Act
6 that—

7 “(aa) meets the require-
8 ments to perform tests of high
9 complexity; and

10 “(bb) is under common own-
11 ership and control as the labora-
12 tory that developed the test.

13 “(2) TEST INSTRUMENT LABELING.—Unless
14 the instrument is the entire test system, the labeling
15 for an instrument is not required to bear the infor-
16 mation indicated in paragraphs (3), (4), (5), (7),
17 (8), (9), (10), (11), (12), and (13) of section
18 809.10(b) of title 21, Code of Federal Regulations
19 (or any successor regulations).

20 “(3) REAGENT LABELING.—For purposes of
21 compliance with subsection (c)(1), the labeling for a
22 reagent intended for use as a replacement in an in
23 vitro clinical test may be limited to that information
24 necessary to identify the reagent adequately and to
25 describe its proper use in the test.

1 “(4) INVESTIGATIONAL USE.—A shipment or
2 other delivery of an in vitro clinical test for inves-
3 tigational use pursuant to section 587S shall be ex-
4 empt from the labeling requirements of subsections
5 (b) and (c)(1) and from any standard promulgated
6 through regulations, except as required under sec-
7 tion 353 of the Public Health Service Act or section
8 587R of this Act.

9 “(5) GENERAL PURPOSE LABORATORY RE-
10 AGENTS.—The labeling of general purpose labora-
11 tory reagents (such as hydrochloric acid) whose uses
12 are generally known by persons trained in their use
13 need not bear the directions for use required by sub-
14 section (c)(1)(A).

15 “(6) OVER-THE-COUNTER TEST SPECIMEN RE-
16 CEPTACLE LABELING.—The labeling for over-the-
17 counter test specimen receptacles for drugs of abuse
18 testing shall bear the name and place of business of
19 the developer included in the registration under sec-
20 tion 587J and any information specified in applica-
21 ble regulations promulgated under this section, in
22 language appropriate for the intended users.

23 “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-
24 PILE.—

1 “(1) IN GENERAL.—The Secretary may grant
2 an exception or alternative to any provision listed in
3 this section, unless explicitly required by a statutory
4 provision outside this subchapter, for specified lots,
5 batches, or other units of an in vitro clinical test, if
6 the Secretary determines that compliance with such
7 labeling requirement could adversely affect the avail-
8 ability of such products that are, or will be, included
9 in the Strategic National Stockpile under section
10 319F–2 of the Public Health Service Act.

11 “(2) REGULATIONS.—The Secretary may issue
12 regulations amending section 809.11 of title 21,
13 Code of Federal Regulations (or any successor regu-
14 lation) to apply in full or in part to in vitro clinical
15 tests and in vitro clinical test developers.

16 “(f) REGULATIONS.—The Secretary shall issue or re-
17 vise regulations related to standardized, general content
18 and format for in vitro clinical test labeling pursuant to
19 this subsection.

20 **“SEC. 587M. ADVERSE EVENT REPORTING.**

21 “(a) IN GENERAL.—Each in vitro clinical test devel-
22 oper shall establish and maintain a system for establishing
23 and maintaining records of adverse events and reporting
24 adverse events in accordance with subsection (b).

1 “(b) ADVERSE EVENT REPORTS.—If a developer re-
2 ceives or otherwise becomes aware of information that rea-
3 sonably suggests that the developer’s in vitro clinical test
4 may have caused or contributed to an adverse event, the
5 developer shall submit an adverse event report to the Sec-
6 retary, in accordance with subsections (c) and (d).

7 “(c) SUBMISSION OF INDIVIDUAL REPORTS.—A de-
8 veloper shall submit an individual adverse event not later
9 than 5 calendar days after the developer receives or be-
10 comes aware of an adverse event that reasonably suggests
11 that an in vitro clinical test may—

12 “(1) have caused or contributed to a patient or
13 user death; or

14 “(2) present an imminent threat to public
15 health.

16 “(d) SUBMISSION OF QUARTERLY REPORTS.—As ap-
17 plicable, a developer shall submit quarterly reports that
18 include any in vitro clinical test errors and serious injuries
19 that occurred during the applicable quarter. Such quar-
20 terly reports shall be submitted not later than the end of
21 the quarter following the quarter in which the developer
22 receives or becomes aware of such adverse events.

23 “(e) DEFINITIONS.—For the purposes of this sec-
24 tion—

1 “(1) the term ‘in vitro clinical test error’ means
2 a failure of an in vitro clinical test to meet its per-
3 formance specifications, or to otherwise perform as
4 intended by the developer, including an inaccurate
5 result resulting from such failure; and

6 “(2) the term ‘serious injury’ means—

7 “(A) a significant delay in a diagnosis that
8 results in the absence, delay, or discontinuation
9 of critical medical treatment or that irreversibly
10 or seriously and negatively alters the course of
11 a disease or condition; or

12 “(B) an injury that—

13 “(i) is life threatening;

14 “(ii) results in permanent impairment
15 of a body function or permanent damage
16 to a body structure; or

17 “(iii) necessitates medical or surgical
18 intervention to preclude permanent impair-
19 ment of a body function or permanent
20 damage to a body structure.

21 “(f) REGULATIONS.—The Secretary shall promulgate
22 regulations to implement this section.

1 **“SEC. 587N. CORRECTIONS AND REMOVALS.**

2 “(a) REGULATIONS.—The Secretary shall promulgate
3 regulations, or amend existing regulations, as appropriate,
4 to implement this section.

5 “(b) REPORTS OF CORRECTIONS AND REMOVALS.—

6 “(1) IN GENERAL.—Each in vitro clinical test
7 developer shall report to the Secretary any correc-
8 tion or removal of an in vitro clinical test under-
9 taken by such developer if the correction or removal
10 was undertaken—

11 “(A) to reduce the risk to health posed by
12 the in vitro clinical test; or

13 “(B) to remedy a violation of this Act
14 caused by the in vitro clinical test which may
15 present a risk to health.

16 “(2) EXCEPTION FOR IN VITRO CLINICAL TESTS
17 OFFERED UNDER A TECHNOLOGY CERTIFICATION
18 ORDER.—For any eligible test offered under a tech-
19 nology certification order under section 587D, a cor-
20 rection and removal report for any correction or re-
21 moval of an in vitro clinical test should demonstrate
22 that the issue or issues causing the correction or re-
23 moval do not adversely impact the ability of other in
24 vitro clinical tests offered under the same technology
25 certification order to meet the applicable standard.

1 “(c) TIMING.—A developer shall submit any report
2 required under this subsection to the Secretary within 15
3 business days of initiating such correction or removal.

4 “(d) RECORDKEEPING.—A developer of an in vitro
5 clinical test that undertakes a correction or removal of an
6 in vitro clinical test which is not required to be reported
7 under this subsection shall keep a record of such correc-
8 tion or removal.

9 “(e) RECALL COMMUNICATIONS.—Upon the vol-
10 untary reporting of a correction or removal by the devel-
11 oper—

12 “(1) the Secretary shall classify such correction
13 or removal under this section within 15 calendar
14 days; and

15 “(2) not later than 45 calendar days after the
16 developer or other responsible party notifies the Sec-
17 retary that it has completed a recall action, the Sec-
18 retary shall provide the developer or other respon-
19 sible party with a written statement closing the re-
20 call action or stating the reasons the Secretary can-
21 not close the recall at that time.

22 **“SEC. 5870. RESTRICTED IN VITRO CLINICAL TESTS.**

23 “(a) APPLICABILITY.—

24 “(1) IN GENERAL.—For the categories of in
25 vitro clinical tests described in paragraph (3) the

1 Secretary may require, in issuing an approval of an
2 in vitro clinical test under section 587B, granting a
3 technology certification order under section 587D, or
4 in issuing a determination under section 587F(a), or
5 by issuing a regulation, that such test be restricted
6 to sale, distribution, or use upon such conditions as
7 the Secretary may prescribe under paragraph (2).

8 “(2) CONDITIONS.— The Secretary may pre-
9 scribe conditions under this section【, based on evi-
10 dence】, with respect to an in vitro clinical test de-
11 scribed in paragraph (3), that are determined 【to be
12 needed】 due to the potential for harmful effect of
13 such test (including any resulting absence, signifi-
14 cant delay, or discontinuation of appropriate medical
15 treatment), and are necessary to ensure that the test
16 meets the applicable standard.

17 “(3) IN VITRO CLINICAL TESTS SUBJECT TO
18 RESTRICTIONS.—The 【restrictions or conditions】
19 authorized under this section may be applied by the
20 Secretary to any high-risk or moderate-risk in vitro
21 clinical test, prescription home-use in vitro clinical
22 test, direct-to-consumer in vitro clinical test, or over-
23 the-counter in vitro clinical test.

24 “(b) LABELING AND ADVERTISING OF A RESTRICTED
25 IN VITRO CLINICAL TEST.—The labeling and advertising

1 of an in vitro clinical test to which restrictions apply under
2 subsection (a) shall bear such appropriate statements of
3 the restrictions as the Secretary may prescribe in an ap-
4 proval under section 587B, an order under section 587D,
5 a determination under section 587F(a), or in regulation,
6 as applicable.

7 “(c) **DEVICE RESTRICTIONS.**—An in vitro clinical
8 test that was offered as a restricted device prior to the
9 date of enactment of this subchapter—

10 “(1) shall continue to comply with the applica-
11 ble restrictions under section 515 or section 520(e)
12 until the this subchapter takes effect; and

13 “(2) except for in vitro clinical tests required to
14 meet section 809.30 of title 21, Code of Federal
15 Regulations prior to the effective date of this sub-
16 chapter specified in section 825(a)(1)(A) of the
17 VALID Act of 2022, such restrictions shall be
18 deemed to be restrictions under this Act as of such
19 effective date.

20 **“SEC. 587P. APPEALS.**

21 “(a) **SIGNIFICANT DECISION.**—

22 “(1) **IN GENERAL.**—The Secretary shall main-
23 tain a substantive summary of the scientific and reg-
24 ulatory rationale for any significant decision of the

1 Food and Drug Administration pursuant to section
2 587F, regarding—

3 “(A) the submission of an application for,
4 or a review of, an in vitro clinical test under
5 section 587B or section 587D;

6 “(B) an exemption under section 587C; or

7 “(C) any requirements for mitigation
8 measures to an in vitro clinical test or category
9 of in vitro clinical tests.

10 Such summaries shall include documentation of sig-
11 nificant controversies or differences of opinion and
12 the resolution of such controversies or differences of
13 opinion.

14 “(2) PROVISION OF DOCUMENTATION.—Upon
15 request, the Secretary shall furnish a substantive
16 summary described in paragraph (1) to the person
17 who has made, or is seeking to make, a submission
18 described in such paragraph.

19 “(3) APPLICATION OF LEAST BURDENSOME RE-
20 QUIREMENTS.—The substantive summary required
21 under this subsection shall include a brief statement
22 regarding how the least burdensome requirements
23 were considered and applied consistent with section
24 587BB(c), as applicable.

25 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

1 “(1) REQUEST FOR SUPERVISORY REVIEW OF
2 SIGNIFICANT DECISION.—A developer may request a
3 supervisory review of the significant decision de-
4 scribed in subsection (a)(1). Such review may be
5 conducted at the next supervisory level or higher
6 above the agency official who made the significant
7 decision.

8 “(2) SUBMISSION OF REQUEST.—A developer
9 requesting a supervisory review under paragraph (1)
10 shall submit such request to the Secretary not later
11 than 30 days after the decision for which the review
12 is requested and shall indicate in the request wheth-
13 er such developer seeks an in-person meeting or a
14 teleconference review.

15 “(3) TIMEFRAME.—The Secretary shall sched-
16 ule an in-person or teleconference review, if so re-
17 quested, not later than 30 days after such request
18 is made. The Secretary shall issue a decision to the
19 developer requesting a review under this subsection
20 not later than 45 days after the request is made
21 under paragraph (1), or, in the case of a developer
22 who requests an in-person meeting or teleconference,
23 30 days after such meeting or teleconference.

24 “(c) ADVISORY PANELS.—The process established
25 under subsection (a) shall permit the appellant to request

1 review by an advisory committee established under section
2 587G when there is a dispute involving substantial sci-
3 entific fact. If an advisory panel meeting is held, the Sec-
4 retary shall make a determination under this subsection
5 not later than **[45]** days after the requested advisory
6 committee meeting has concluded.

7 **[“(d) LEAST BURDENSOME REVIEW.—**Any devel-
8 oper who has submitted an application under section 587B
9 or 587D may request a supervisory review of a request
10 for additional information during an evaluation of such
11 submission within 60 calendar days of receipt of the addi-
12 tional information request from the Secretary.]

13 **[“(e) AVAILABILITY OF ALL REMEDIES.—**The proce-
14 dures set forth in this section shall be in addition to, and
15 not in lieu of, other remedies available to the developer.]

16 **“SEC. 587Q. ACCREDITED PERSONS.**

17 **“(a) IN GENERAL.—**

18 **“(1) REVIEW OF APPLICATIONS.—**

19 **“(A) ACCREDITATION FOR APPLICATION**
20 **REVIEW.—**Beginning on the date of enactment
21 of the VALID Act of 2022, the Secretary shall
22 accredit persons for the purpose of reviewing
23 applications for premarket approval under sec-
24 tion 587B and applications for technology cer-
25 tification under section 587D and making rec-

1 ommendations to the Secretary with respect to
2 the approval or issuance of such applications or
3 orders.

4 “(B) REQUIREMENT REGARDING REVIEW
5 RECOMMENDATIONS.—

6 “(i) IN GENERAL.—In making a rec-
7 ommendation to the Secretary under this
8 section, an accredited person shall notify
9 the Secretary in writing of the reasons for
10 the recommendation concerning the appli-
11 cation.

12 “(ii) TIME PERIOD FOR REVIEW.—
13 Not later than 30 calendar days after the
14 date on which the Secretary is notified of
15 a recommendation under this section with
16 respect to an application for premarket ap-
17 proval or technology certification, the Sec-
18 retary shall make a determination with re-
19 spect to the application.

20 “(2) INSPECTIONS.—

21 “(A) ACCREDITATION FOR INSPECTIONS.—
22 During the period beginning on the date of en-
23 actment of the VALID Act of 2022, the Sec-
24 retary shall accredit persons for the purpose of
25 conducting inspections of establishments of de-

1 velopers required to register pursuant to section
2 587J.

3 “(B) EFFECT OF ACCREDITATION.—

4 “(i) IN GENERAL.—Persons accredited
5 under subparagraph (A) to conduct inspec-
6 tions, when conducting such inspections,
7 shall record in writing their specific obser-
8 vations and shall present their observations
9 to the designated representative of the in-
10 spected establishment.

11 “(ii) INSPECTION REPORT REQUIRE-
12 MENTS.—Each person accredited under
13 this paragraph shall prepare and submit to
14 the Secretary an inspection report in a
15 form and manner designated by the Sec-
16 retary for conducting inspections, taking
17 into consideration the goals of inter-
18 national harmonization of quality systems
19 standards. Any official classification of the
20 inspection shall be determined by the Sec-
21 retary. Any statement or representation
22 made by an employee or agent of an estab-
23 lishment to a person accredited to conduct
24 inspections shall be subject to section 1001
25 of title 18, United States Code.

1 “(C) SAVINGS CLAUSE.—Nothing in this
2 section affects the authority of the Secretary to
3 inspect any in vitro clinical test developer or
4 other person registered under section 587J.

5 “(D) INSPECTION LIMITATIONS.—The Sec-
6 retary shall ensure that inspections carried out
7 under this section—

8 “(i) are not duplicative of inspections
9 carried out under section 353 of the Public
10 Health Service Act; and

11 “(ii) are limited to the data and infor-
12 mation necessary—

13 “(I) for routine surveillance ac-
14 tivities of establishments associated
15 with an approved application under
16 section 587B or a technology certifi-
17 cation order under section 587D; or

18 “(II) to meet the requirements to
19 receive premarket approval under sec-
20 tion 587B or a technology certifi-
21 cation order under section 587D, as
22 applicable.

23 “(b) ACCREDITATION.—

24 “(1) ACCREDITATION PROGRAM.—

1 “(A) IN GENERAL.—The Secretary may
2 provide for accreditation under this section
3 through programs administered by the Food
4 and Drug Administration, by other non-Federal
5 government agencies, or by qualified nongovern-
6 mental organizations. A person may be accred-
7 ited for the review of both applications sub-
8 mitted under sections 587B and 587D as de-
9 scribed in subsection (a)(1)(A) and to conduct
10 inspection activities under subsection (a)(2)(A),
11 or for a subset of such review or activities.

12 “(B) ELIGIBLE PERSONS.—Not later than
13 1 year after the date of enactment of the
14 VALID Act of 2022, the Secretary shall issue
15 draft regulations on the criteria that the Sec-
16 retary will use to accredit or deny accreditation
17 to a person who requests such accreditation
18 under subsection (a), and not later than one
19 year after the close of the comment period for
20 the draft regulations issued in this section,
21 issue final regulations.

22 “(C) REQUIREMENTS.—

23 “(i) IN GENERAL.—The Secretary
24 shall not accredit or maintain accreditation
25 for a person unless such person meets the

1 minimum qualifications required under
2 subsection (c).

3 “(ii) SCOPE OF ACCREDITATION.—

4 The accreditation of a person under this
5 section shall specify the particular activi-
6 ties under subsection (a) for which such
7 person is accredited.

8 “(D) PUBLIC LIST.—The Secretary shall
9 publish on the website of the Food and Drug
10 Administration a list of persons who are accred-
11 ited under this section. Such list shall be up-
12 dated on at least a monthly basis. The list shall
13 specify the particular activity or activities under
14 this section for which the person is accredited.

15 “(2) ACCREDITATION PROCESS.—

16 “(A) ACCREDITATION PROCESS GUID-
17 ANCE.—The Secretary shall—

18 “(i) not later than 180 days after the
19 date of enactment of the VALID Act of
20 2022, issue draft guidance specifying the
21 process for submitting a request for each
22 type of accreditation and reaccreditation
23 under this section, including the form and
24 content of information to be submitted in
25 such a request; and

1 “(ii) not later than 1 year after the
2 close of the comment period for the draft
3 guidance, issue final guidance.

4 “(B) RESPONSE TO REQUEST.—The Sec-
5 retary shall respond to a request for accredita-
6 tion or reaccreditation within 60 calendar days
7 of the receipt of the request. The Secretary’s
8 response may be to accredit or reaccredit the
9 person, to deny accreditation, or to request ad-
10 ditional information in support of the request.
11 If the Secretary requests additional informa-
12 tion, the Secretary shall respond within 60 cal-
13 endar days of receipt of such additional infor-
14 mation to accredit or deny the accreditation.

15 “(C) TYPE OF ACCREDITATION.—The ac-
16 creditation or reaccreditation of a person shall
17 specify the particular activity or activities under
18 subsection (a) for which such person is accred-
19 ited, and shall include any limitation to certain
20 eligible in vitro clinical tests. The Secretary
21 shall issue guidance on the factors that the Sec-
22 retary intends to use in determining whether a
23 category of in vitro clinical tests or a technology
24 type pursuant to 587D is eligible for review by
25 an accredited person.

1 “(D) AUDIT.—The Secretary may audit
2 the performance of persons accredited under
3 this section for purposes of ensuring that such
4 persons continue to meet the published criteria
5 for accreditation, and may modify the scope or
6 particular activities for which a person is ac-
7 credited if the Secretary determines that such
8 person fails to meet one or more criteria for ac-
9 creditation.

10 “(E) SUSPENSION OR WITHDRAWAL.—The
11 Secretary may suspend or withdraw accredita-
12 tion of any person accredited under this section,
13 after providing notice and an opportunity for an
14 informal hearing, when such person is substan-
15 tially not in compliance with the requirements
16 of this section or the published criteria for ac-
17 creditation, or poses a threat to public health,
18 or fails to act in a manner that is consistent
19 with the purposes of this section.

20 “(F) REACCREDITATION.—Accredited per-
21 sons may be initially accredited for up to 3
22 years. After expiration of such initial period,
23 persons may be reaccredited for unlimited addi-
24 tional 3-year periods, as determined by the Sec-
25 retary.

1 “(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

2 “(1) ELIGIBILITY.—An accredited person, at a
3 minimum, shall—

4 “(A) not be an employee of the Federal
5 Government;

6 “(B) not engage in the activities of a de-
7 veloper, as defined in section 587;

8 “(C) not be a person required to register
9 under section 587J;

10 “(D) not be owned or controlled by, and
11 shall have no organizational, material, or finan-
12 cial affiliation with, an in vitro clinical test de-
13 veloper or other person required to register
14 under section 587J;

15 “(E) be a legally constituted entity per-
16 mitted to conduct the activities for which it
17 seeks accreditation;

18 “(F) ensure that the operations of such
19 person are in accordance with generally accept-
20 ed professional and ethical business practices;
21 and

22 “(G) include in its request for accredita-
23 tion a commitment to, at the time of accredita-
24 tion and at any time it is performing activities
25 pursuant to this section—

1 “(i) certify that the information re-
2 ported to the Secretary accurately reflects
3 the data or protocol reviewed, and the doc-
4 umented inspection findings, as applicable;

5 “(ii) limit work to that for which com-
6 petence and capacity are available;

7 “(iii) treat information received or
8 learned, records, reports, and recommenda-
9 tions as proprietary information of the per-
10 son submitting such information; and

11 “(iv) in conducting the activities for
12 which the person is accredited in respect to
13 a particular in vitro clinical test, protect
14 against the use of any employee or consult-
15 ant who has a financial conflict of interest
16 regarding that in vitro clinical test.

17 “(2) WAIVER.—The Secretary may waive any
18 requirements in subparagraphs (A), (B), (C), or (D)
19 of paragraph (1) upon making a determination that
20 such person has implemented appropriate controls
21 sufficient to ensure a competent and impartial re-
22 view, such as when such person has established suf-
23 ficient processes and protocols to separate activities
24 to develop in vitro clinical tests and the activities for
25 such person would be accredited under subsection

1 (a) and discloses applicable information under this
2 section.

3 “(d) COMPENSATION OF ACCREDITED PERSONS.—

4 “(1) IN GENERAL.—Compensation of any ac-
5 credited person shall not take into account, whether
6 directly or indirectly, the results of any review or in-
7 spection.

8 “(2) REVIEW ACCREDITATION.—Compensation
9 of an accredited person who reviews an application
10 for premarket approval submitted under section
11 587B or an application for technology certification
12 submitted under section 587D shall be determined
13 by agreement between the accredited person and the
14 person who engages the services of the accredited
15 person, and shall be paid by the person who engages
16 such services.

17 “(3) INSPECTION ACCREDITATION.—Compensa-
18 tion of an accredited person who is conducting an
19 inspection under section 704 shall be determined by
20 agreement between the accredited person and the
21 person who engages the services of the accredited
22 person, and shall be paid by the person who engages
23 such services.

24 “(e) INFORMATION SHARING AGREEMENTS.—An ac-
25 credited person may enter into an agreement with a devel-

1 oper for the accredited person to provide information to
2 the comprehensive test information system under section
3 587U, including any requirements under section 587J.

4 **“SEC. 587R. RECOGNIZED STANDARDS.**

5 “(a) IN GENERAL.—The Secretary may recognize all
6 or part of appropriate standards established by nationally
7 or internationally recognized standards development orga-
8 nizations for which a person may submit a declaration of
9 conformity in order to meet a requirement under this sub-
10 chapter to which that standard is applicable. Standards
11 for in vitro diagnostic devices previously recognized under
12 section 514(c) shall be considered recognized standards
13 under this section. Recognized and proposed standards
14 shall be accessible to the public at no charge. The applica-
15 tion of any such consensus standard shall only apply pro-
16 spectively. The Secretary shall issue regulations estab-
17 lishing the criteria, and guidance establishing the process,
18 for such recognition and adoption.

19 **【“(b) ORDER PROCESS.—In 【recognition of】 a**
20 standard under subsection (a) or withdrawal of recogni-
21 tion of such a standard, the Secretary shall issue a draft
22 order proposing to establish a standard and shall provide
23 for a comment period of not less than **【60】/【70】** calendar
24 days. The Secretary may seek the recommendation of an
25 advisory committee under section 587H concerning a pro-

1 posed standard either prior to or after issuance of a pro-
2 posed order. After considering the comments and within
3 90 days of the close of the comment period, the Secretary
4 shall issue a final order adopting the proposed standard,
5 adopting a modification of the proposed standard or termi-
6 nating the proceeding.】

7 “(c) AMENDMENT PROCESS.—The procedures estab-
8 lished in this section or in regulation or guidance issued
9 under this section shall apply to amendment of an existing
10 standard.

11 **“SEC. 587S. INVESTIGATIONAL USE.**

12 “(a) IN GENERAL.—Subject to the conditions pre-
13 scribed in subsections (c), (d), (e), (f), and (g) of this sec-
14 tion, an in vitro clinical test for investigational use shall
15 be exempt from the requirements of this subchapter other
16 than sections 587A, 587P, 587U, and 587V. The Sec-
17 retary may amend parts 50, 54, and 56 of title 21 of the
18 Code of Federal Regulations, or any successor regulations,
19 to apply to in vitro clinical tests to permit the investiga-
20 tional use of such tests by experts qualified by scientific
21 training and experience.

22 “(b) REGULATIONS.—

23 “(1) IN GENERAL.—Not later than 2 years
24 after the date of enactment of the VALID Act of
25 2022, the Secretary shall promulgate regulations, or

1 amend existing regulations, to implement this sec-
2 tion.

3 “(2) VARIATION.—The requirements in the reg-
4 ulations promulgated under this section shall take
5 into account variations based on—

6 “(A) the scope and duration of clinical
7 testing to be conducted under investigation that
8 is the subject of such application;

9 “(B) the number of human subjects that
10 are to be involved in such testing;

11 “(C) the need to permit changes to be
12 made to the in vitro clinical test involved during
13 testing conducted in accordance with a plan re-
14 quired under subsection (c)(5); or

15 “(D) whether the clinical testing of such in
16 vitro clinical test is for the purpose of devel-
17 oping data to obtain approval to offer such test.

18 “(c) APPLICATION FOR INVESTIGATIONAL USE.—
19 The following shall apply with respect to in vitro clinical
20 tests for investigational use:

21 “(1) SIGNIFICANT RISK AND OTHER STUD-
22 IES.—In the case of an in vitro clinical test the in-
23 vestigational use of which poses a significant risk to
24 the human subject, a sponsor of an investigation of
25 such a test seeking an investigational use exemption

1 shall submit to the Secretary an investigational use
2 application with respect to the in vitro clinical test
3 in accordance with paragraphs (3) and (4). For pur-
4 poses of this subparagraph, the term ‘significant
5 risk’ means, with respect to an in vitro clinical test
6 that is a high-risk in vitro clinical test, and that the
7 use of such in vitro clinical test—

8 “(A) is of substantial importance in per-
9 forming an activity or activities described in
10 section 201(ss)(1) for, a serious or life-threat-
11 ening disease or condition without confirmation
12 of the diagnosis by a medically established diag-
13 nostic product or procedure;

14 “(B) requires an invasive sampling proce-
15 dure that presents a significant risk to the
16 human subject, provided that routine
17 venipuncture shall not be considered an invasive
18 sampling procedure; or

19 “(C) otherwise presents a reasonably fore-
20 seeable serious risk to the health of a human
21 subject.

22 “(2) NON-SIGNIFICANT RISK STUDIES.—In the
23 case of an in vitro clinical test, the investigational
24 use of which is not described in paragraph (1)—

1 “(A) the sponsor of such investigation
2 shall—

3 “(i) ensure such investigation is con-
4 ducted in compliance with an investiga-
5 tional plan approved by an institutional re-
6 view committee and the labeling of the in
7 vitro clinical test involved clearly and con-
8 spicuously states, ‘For investigational use’,
9 as specified in paragraph (4)(A)(ii);

10 “(ii) ensure each investigator obtains
11 informed consent as required under part
12 50 of title 21, Code of Federal Regulations
13 (or any successor regulations), subject to
14 the exceptions set forth in paragraphs
15 (5)(A)(iii) and (5)(B); and

16 “(iii) establish and maintain records
17 with respect to all requirements in this
18 subparagraph; and

19 “(B) the sponsor may rely on any excep-
20 tion or exemption described in paragraph
21 (5)(B) or as established by the Secretary in
22 regulations issued under subsection (b).

23 “(3) APPLICATION.—An investigational use ap-
24 plication shall be submitted in such time and man-
25 ner and contain such information as the Secretary

1 may require in regulation, and shall include an in-
2 vestigational plan for proposed clinical testing and
3 assurances that the sponsor submitting the applica-
4 tion will—

5 “(A) establish and maintain records rel-
6 evant to the investigation of such in vitro clin-
7 ical test; and

8 “(B) submit to the Secretary annual re-
9 ports of data obtained as a result of the inves-
10 tigational use of the in vitro clinical test during
11 the period covered by the exemption that the
12 Secretary reasonably determines will enable the
13 Secretary—

14 “(i) to ensure compliance with the
15 conditions for the exemption specified in
16 paragraph (3);

17 “(ii) to review the progress of the in-
18 vestigation involved; and

19 “(iii) to evaluate the ability to meet
20 the applicable standard.

21 “(4) CONDITIONS FOR EXEMPTION.—

22 “(A) IN GENERAL.—An application for an
23 investigational use exemption with respect to a
24 significant risk study shall be granted if each of
25 the following conditions is met:

1 “(i) The risks to the subjects of the in
2 vitro clinical test are outweighed by the an-
3 ticipated benefits of the test to the subjects
4 and the importance of the knowledge to be
5 gained, and adequate assurance of in-
6 formed consent is provided in accordance
7 with paragraphs (6)(A)(iii) and (6)(B).

8 “(ii) The proposed labeling for the in
9 vitro clinical test involved clearly and con-
10 spicuously states ‘For investigational use’.

11 “(iii) Such other requirements the
12 Secretary determines—

13 “(I) are necessary for the protec-
14 tion of the public health and safety;
15 and

16 “(II) do not unduly delay inves-
17 tigation.

18 “(B) CERTAIN SIGNIFICANT RISK STUDIES
19 OF IN VITRO CLINICAL TESTS FOR AN UNMET
20 NEED.—The Secretary shall not impose a limit
21 on the sample size for a significant risk study
22 of an in vitro clinical test that has received
23 breakthrough designation under section 587I.

24 “(5) COORDINATION WITH INVESTIGATIONAL
25 NEW DRUG APPLICATIONS.—Any requirement for

1 the submission of a report to the Secretary pursuant
2 to an application for an investigational new drug ex-
3 emption involving an in vitro clinical test shall su-
4 persede the reporting requirement in paragraph
5 (2)(B), but only to the extent the requirement with
6 respect to the application for exemption with respect
7 to the drug is duplicative of the reporting require-
8 ment under such paragraph.

9 “(6) INVESTIGATIONAL PLAN, PROCEDURES,
10 AND CONDITIONS.—With respect to an investiga-
11 tional plan submitted under paragraph (3), the
12 sponsor submitting such plan shall—

13 “(A) promptly notify the Secretary of the
14 approval or the suspension or termination of
15 the approval of such plan by an institutional re-
16 view committee;

17 “(B) in the case of an in vitro clinical test
18 made available to investigators for clinical test-
19 ing, assurances that—

20 “(i) all investigators will comply with
21 this section, regulations promulgated or re-
22 vised under this section, and applicable
23 human subjects regulations; and

24 “(ii) the investigator will ensure
25 that—

1 “(iii) there is not sufficient time to
2 obtain such consent from a representative
3 of such subject.

4 “(d) REVIEW OF APPLICATIONS.—

5 “(1) IN GENERAL.—The Secretary may issue
6 an order approving an investigation as proposed, ap-
7 proving it with conditions or modifications, or dis-
8 approving it.

9 “(2) FAILURE TO ACT.—Unless the Secretary,
10 not later than the date that is 30 calendar days
11 after the date of the submission of an application for
12 an investigational use exemption that meets the re-
13 quirements of subsection (c)(2), issues an order
14 under paragraph (1) and notifies the sponsor sub-
15 mitting the application, the application shall be
16 treated as approved as of such date without further
17 action by the Secretary.

18 “(3) DENIAL.—The Secretary may deny an in-
19 vestigational use application submitted under this
20 subsection if the Secretary determines that the in-
21 vestigation with respect to which the application is
22 submitted does not conform to the requirements of
23 subsection (c). A notification of such denial sub-
24 mitted to the sponsor with respect to such a request
25 shall contain the order of disapproval and a complete

1 statement of the reasons for the Secretary's denial
2 of the application.

3 “(e) WITHDRAWAL OF EXEMPTION.—

4 “(1) IN GENERAL.—The Secretary may, by ad-
5 ministrative order, withdraw an exemption approved
6 under this section with respect to an in vitro clinical
7 test, including an exemption treated as approved
8 based on the Secretary's failure to act pursuant to
9 subsection (d)(2), if the Secretary determines that
10 an investigation conducted under such an exemption
11 does not meet the applicable conditions under sub-
12 section (c)(3) for such exemption.

13 “(2) OPPORTUNITY TO BE HEARD.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), an order withdrawing an investiga-
16 tional use exemption granted under this section
17 may be issued only after the Secretary provides
18 the sponsor of the in vitro clinical test with an
19 opportunity for an informal hearing.

20 “(B) EXCEPTION.—An order referred to in
21 subparagraph (A) with respect to an investiga-
22 tional use exemption granted under this section
23 may be issued on a preliminary basis before the
24 provision of an opportunity for an informal
25 hearing if the Secretary determines that the

1 continuation of testing under the exemption will
2 result in an unreasonable risk to the public
3 health. The Secretary will provide an oppor-
4 tunity for an informal hearing promptly fol-
5 lowing any preliminary action under this sub-
6 paragraph.

7 “(f) CHANGES.—

8 “(1) IN GENERAL.—The regulations promul-
9 gated under subsection (b) shall provide, with re-
10 spect to an in vitro clinical test for which an exemp-
11 tion under this subsection is in effect, procedures
12 and conditions under which changes are allowed
13 without the additional approval of an application for
14 an exemption or submission of a supplement to such
15 an application. Such regulations shall provide that
16 such a change may be made if—

17 “(A) the sponsor determines, on the basis
18 of credible information (as defined in regula-
19 tions) that the change meets the conditions
20 specified in paragraph (2); and

21 “(B) the sponsor submits to the Secretary,
22 not later than 8 calendar days after making the
23 change, a notice of the change.

24 “(2) CONDITIONS.—The conditions specified in
25 this paragraph are that—

1 “(A) in the case of developmental changes
2 to an in vitro clinical test, including manufac-
3 turing changes, the changes—

4 “(i) do not constitute a significant
5 change in design or in basic principles of
6 operation;

7 “(ii) do not affect the rights, safety,
8 or welfare of the human subjects involved
9 in the investigation; and

10 “(iii) are made in response to infor-
11 mation gathered during the course of an
12 investigation; and

13 “(B) in the case of changes to clinical pro-
14 tocols applicable to the test, the changes do not
15 affect—

16 “(i) the validity of data or information
17 resulting from the completion of an ap-
18 proved clinical protocol;

19 “(ii) the scientific soundness of a plan
20 submitted under subsection (c)(3); or

21 “(iii) the rights, safety, or welfare of
22 the human subjects involved in the inves-
23 tigation.

24 “(g) CLINICAL HOLD.—

1 “(1) IN GENERAL.—At any time, the Secretary
2 may impose a clinical hold with respect to an inves-
3 tigation of an in vitro clinical test if the Secretary
4 makes a written determination described in para-
5 graph (2). The Secretary shall, in imposing such
6 clinical hold, specify the basis for the clinical hold,
7 including the specific information available to the
8 Secretary which served as the basis for such clinical
9 hold, and confirm such determination in writing.
10 The applicant may immediately appeal any such de-
11 termination pursuant to section 587P.

12 “(2) DETERMINATION.—

13 “(A) IN GENERAL.—For purposes of para-
14 graph (1), a determination described in this
15 subparagraph with respect to a clinical hold is
16 a determination that, based on valid scientific
17 evidence, the in vitro clinical test involved rep-
18 resents an unreasonable risk to the safety of
19 the persons who are the subjects of the clinical
20 investigation, taking into account the qualifica-
21 tions of the clinical investigators, information
22 about the in vitro clinical test, the design of the
23 clinical investigation, the condition for which
24 the in vitro clinical test is to be investigated,
25 and the health status of the subjects involved.

1 “(B) REMOVAL OF CLINICAL HOLD.—Any
2 written request to the Secretary from the spon-
3 sor of an investigation that a clinical hold be re-
4 moved shall receive a decision, in writing and
5 specifying the reasons therefor, within 30 days
6 after receipt of such request. Any such request
7 shall include sufficient information to support
8 the removal of such clinical hold.

9 **【“SEC. 587T. COLLABORATIVE COMMUNITIES FOR IN VITRO**
10 **CLINICAL TESTS.**

11 **【“(a) IN GENERAL.—】**

12 【“(1) For the purposes of facilitating commu-
13 nity solutions and decision making with respect to in
14 vitro clinical tests, the Secretary may participate in
15 collaborative communities comprised of public and
16 private participants that may provide recommenda-
17 tions and other advice to the Secretary on the devel-
18 opment and regulation of in vitro clinical tests.】

19 【“(2) A collaborative community under this
20 section shall have broad representation of interested
21 private and public-sector stakeholder communities
22 and may include patients, care partners, academics,
23 health care professionals, health care systems,
24 payors, Federal and State agencies, entities respon-
25 sible for accrediting clinical laboratories, inter-

1 national regulatory bodies, test developers, or other
2 interested entities or communities.】

3 【“(b) GUIDANCE.—The Secretary shall issue a draft
4 guidance not later than 180 days after the date of enact-
5 ment of the VALID Act of 2022, addressing the participa-
6 tion process and framework to build consensus, and how
7 the Secretary may consider, review, and implement rec-
8 ommendations under subsection (c).】

9 【“(c) RECOMMENDATIONS.—A collaborative commu-
10 nity for in vitro clinical tests may make recommendations
11 to the Secretary on matters including—】

12 【“(1) mitigating measures for in vitro clinical
13 tests;】

14 【“(2) standards development activities and per-
15 formance standards for in vitro clinical tests or
16 groups of such tests;】

17 【“(3) scientific and clinical evidence to support
18 new claims for in vitro clinical tests;】

19 【“(4) new technologies and methodologies re-
20 lated to in vitro clinical tests;】

21 【“(5) stakeholder communication and engage-
22 ment; and】

23 【“(6) development of effective policies and
24 processes, including regarding development of in
25 vitro clinical tests, and regulation of such tests in

1 accordance with least burdensome principles de-
2 scribed in section 587B(j).】

3 【“(d) USE BY SECRETARY.—】

4 【“(1) IN GENERAL.—The Secretary may adopt
5 recommendations made under subsection (b), or oth-
6 erwise incorporate the feedback from collaborative
7 communities into regulatory decision making,
8 through rulemaking or guidance, as appropriate.】

9 【“(2) CLARIFICATION.—The Secretary is not
10 required to adopt recommendations submitted by
11 collaborative communities.】

12 【“(e) TRANSPARENCY.—The Secretary shall—】

13 【“(1) publish on the website of the Food and
14 Drug Administration matters for which it is seeking
15 comments or recommendations;】

16 【“(2) maintain a list of all collaborative com-
17 munities in which the Secretary participates and
18 make such list available on the website of the Food
19 and Drug Administration; and】

20 【“(3) post on the website of the Food and
21 Drug Administration at least once every year a re-
22 port on the recommendations it has adopted and rec-
23 ommendations it has not adopted from collaborative
24 communities.】

1 【“(f) PARTICIPATION.—The Secretary may partici-
2 pate in a collaborative community only if such community
3 requires members to disclose conflicts of interest and has
4 established a process to address conflicts of interest.】

5 【“(g) EXEMPTION.—The collaborative communities
6 established and used in accordance with this section shall
7 be exempt from the Federal Advisory Committee Act (5
8 U.S.C. App.).】

9 **“SEC. 587U. COMPREHENSIVE TEST INFORMATION SYSTEM.**

10 “(a) ESTABLISHMENT.—Not later than 2 years after
11 the date of enactment of the VALID Act of 2022, the Sec-
12 retary shall make available a comprehensive test informa-
13 tion system for in vitro clinical tests that is designed to—

14 “(1) provide a transparent interface on the
15 website of the Food and Drug Administration for
16 stakeholders, to the extent permitted by applicable
17 law, which may include access to the—

18 “(A) regulatory pathway designation infor-
19 mation for each in vitro clinical test or tests
20 with the same intended use;

21 “(B) registration and listing information
22 provided by developers under section 587J, in-
23 cluding the use of a link for labels;

24 “(C) adverse event reports submitted
25 under section 587M, as appropriate;

1 “(D) reports of corrections and removals
2 submitted under section 587N; and

3 “(E) other information pertaining to an in
4 vitro clinical test or tests with the same indica-
5 tions for use, as the Secretary determines ap-
6 propriate; and

7 “(2) provide a secure portal for electronic sub-
8 mission, including applications and other in vitro
9 clinical test submissions, registration and listing in-
10 formation, and adverse event reports, which provides
11 protections from unauthorized disclosure of informa-
12 tion, including of—

13 “(A) trade secret or commercial confiden-
14 tial information; and

15 “(B) national security, countermeasure, or
16 other information restricted from disclosure
17 pursuant to any provision of law.

18 “(b) SUBMISSION FUNCTION.—The comprehensive
19 test information system shall serve as the electronic sub-
20 mission service for test developers submitting information
21 for applications under sections 587B and 587D.

22 **“SEC. 587V. PREEMPTION.**

23 “(a) IN GENERAL.—Except as provided in subsection
24 (b), no State, Tribal, or local government (or political sub-

1 division thereof) may establish or continue in effect any
2 requirement that—

3 “(1) is different from, or in addition to, any re-
4 quirement applicable to an in vitro clinical test
5 under this Act; or

6 “(2) with respect to the analytical validity, clin-
7 ical validity, or safety for individuals who come into
8 contact with such an in vitro clinical test under this
9 Act.

10 “(b) EXCEPTIONS.—Subsection (a) shall not be con-
11 strued to affect the authority of a State, Tribal, or local
12 government—

13 “(1) to license laboratory personnel, health care
14 practitioners, or health care facilities or to regulate
15 any aspect of a health care practitioner-patient rela-
16 tionship;

17 “(2) to enforce laws of general applicability,
18 such as zoning laws, environmental laws, labor laws,
19 and general business laws; or

20 “(3) to authorize laboratories to develop and
21 perform an in vitro clinical test, pursuant to a law
22 enacted by a State prior to January 1, 2022, as long
23 as such law does not impose requirements that are
24 different from any requirement applicable to an in
25 vitro clinical test under this Act.

1 “(c) CLARIFICATION.—Nothing in this section shall
2 be construed to—

3 “(1) modify any action for damages or the li-
4 ability of any person under the law of any State; or

5 “(2) shift liability to health care practitioners
6 or other users.

7 **“SEC. 587W. ADULTERATION.**

8 “An in vitro clinical test shall be deemed to be adul-
9 terated:

10 “(1) If it consists in whole or in part of any
11 filthy, putrid, or decomposed substance.

12 “(2) If it has been developed, prepared, packed,
13 or held under insanitary conditions whereby it may
14 have been contaminated with filth, or whereby it
15 may have been rendered injurious to health.

16 “(3) If its container or package is composed, in
17 whole or in part, of any poisonous or deleterious
18 substance which may render the contents injurious
19 to health.

20 “(4) If it bears or contains, for purposes of
21 coloring only, a color additive which is unsafe within
22 the meaning of section 721(a).

23 “(5) If its analytical or clinical validity, as ap-
24 plicable, or with respect to a specimen receptacle, its

1 safety, falls below that which it purports or is rep-
2 resented to possess.

3 “(6) If it is required to be, declared to be, pur-
4 ports to be, or is represented as being, in conformity
5 with any performance standard established or recog-
6 nized under section 587R and is not in conformity
7 with such standard.

8 “(7) If it is required to be in compliance with
9 mitigating measures established under section 587E
10 and is not in conformity with such mitigating meas-
11 ures.

12 “(8) If it fails to have in effect an approved
13 premarket application under section 587B unless
14 such in vitro clinical test is in compliance with the
15 requirements for—

16 “(A) offering without an approved pre-
17 market application under section 587C or
18 587D;

19 “(B) an exemption from premarket ap-
20 proval under section 587C or 587G;

21 “(C) emergency use pursuant to an au-
22 thorization under section 564; or

23 “(D) investigational use pursuant to sec-
24 tion 587S.

1 “(9) If it is not in conformity with any condi-
2 tion established under section 587B, 587D, or 564.

3 “(10) If it purports to be an in vitro clinical
4 test subject to an exemption under section 587C and
5 it fails to meet or maintain any criteria, condition,
6 or requirement of such exemption.

7 “(11) If it has been granted an exemption
8 under section 587S for investigational use, and the
9 person granted such exemption or any investigator
10 who uses such in vitro clinical test under such ex-
11 emption fails to comply with a requirement pre-
12 scribed by or under such section.

13 “(12) If it fails to meet the quality require-
14 ments prescribed in or established under section
15 587K (as applicable), or the methods used in, or fa-
16 cilities or controls used for, its development, pack-
17 aging, storage, or installation are not in conformity
18 with applicable requirements established under such
19 section.

20 “(13) If it has been developed, processed, pack-
21 aged, or held in any establishment, factory, or ware-
22 house and the owner, operator or agent of such es-
23 tablishment, factory, or warehouse delays, denies, or
24 limits an inspection, or refuses to permit entry or in-
25 spection.

1 “(14) If it is not in compliance with any restric-
2 tion required under section 5870.

3 **“SEC. 587X. MISBRANDING.**

4 “An in vitro clinical test shall be deemed to be mis-
5 branded:

6 “(1) If its labeling is false or misleading in any
7 particular.

8 “(2) If in a package form unless it bears a label
9 containing—

10 “(A) the name and place of business of the
11 test developer, packager, or distributor; and

12 “(B) an accurate statement of the quantity
13 of contents in terms of weight, measure, or nu-
14 merical count with respect to small packages,
15 unless an exemption is granted by the Secretary
16 by the issuance of guidance.

17 “(3) If any word, statement, or other informa-
18 tion required by or under authority of this Act to
19 appear on the label or labeling, including a test re-
20 port, is not prominently placed thereon with such
21 conspicuousness (as compared with other words,
22 statements, designs, or devices, in the labeling) and
23 in such terms as to render it likely to be read and
24 understood by the ordinary individual under cus-
25 tomary conditions of purchase and use.

1 “(4) Unless its labeling bears adequate direc-
2 tions for use and such adequate warnings as are
3 necessary for the protection of users of the in vitro
4 clinical test and recipients of the results of such in
5 vitro clinical test, including patients, consumers, do-
6 nors, and related health care professionals. Required
7 labeling for in vitro clinical tests intended for use in
8 health care facilities, blood establishments, or by a
9 health care professional may be made available solely
10 by electronic means, provided that the labeling com-
11 plies with all applicable requirements of law, and
12 that the test developer, or distributor affords such
13 users the opportunity to request the labeling in
14 paper form, and after such request, promptly pro-
15 vides the requested information without additional
16 cost.

17 “(5) If **【**there is a reasonable probability that
18 it could cause**】** serious or adverse health con-
19 sequences or death, including through absence,
20 delay, or discontinuation in diagnosis or treatment,
21 when used in the manner prescribed, recommended,
22 or suggested in the labeling thereof.

23 “(6) If it was developed, sterilized, packaged,
24 repackaged, relabeled, installed, or imported in an
25 establishment not duly registered under section

1 587J or it was not included in a listing under sec-
2 tion 587J, in accordance with timely reporting re-
3 quirements under this subchapter.

4 “(7) In the case of any in vitro clinical test sub-
5 ject to restrictions under section 587O, (1) if its ad-
6 vertising is false or misleading in any particular, (2)
7 if it is offered for clinical use, sold, distributed, or
8 used in violation of such restrictions, or (3) unless
9 the test developer or distributor includes in all ad-
10 vertisements and other descriptive printed matter
11 that such person issues or causes to be issued, a
12 brief statement of the intended uses of the in vitro
13 clinical test and relevant warnings, precautions, side
14 effects, and contraindications. This subsection shall
15 not be applicable to any printed matter that the Sec-
16 retary determines to be labeling as defined in section
17 201(m).

18 “(8) If it is subject to a mitigating measure es-
19 tablished under section 587E and does not bear such
20 labeling as may be prescribed in such mitigating
21 measure.

22 “(9) If it is subject to a standard established
23 under section 587R and it does not bear such label-
24 ing as may be prescribed in such standard.

1 “(10) Unless it bears such labeling as may be
2 required by or established under an applicable label-
3 ing requirement under this Act.

4 “(11) If there was a failure to comply with any
5 requirement prescribed under section 587D, 587J,
6 587K, 587L, 587M, 587N, 587Y, 587Z, 587AA, or
7 to provide any report, material, or other information
8 required with respect to in vitro clinical tests under
9 this subchapter.

10 **“SEC. 587Y. POSTMARKET SURVEILLANCE.**

11 “(a) IN GENERAL.—

12 “(1) IN GENERAL.—In addition to other appli-
13 cable requirements under this Act, the Secretary
14 may issue an order requiring a developer of a high-
15 risk or moderate-risk in vitro clinical test to conduct
16 postmarket surveillance of such in vitro clinical test,
17 if the failure of the in vitro clinical test to meet the
18 applicable standard is reasonably likely to result in
19 serious adverse health consequences or death from
20 use of such in vitro clinical test.

21 “(2) CONSIDERATION.—In determining whether
22 to require a developer to conduct postmarket surveil-
23 lance of an in vitro clinical test, the Secretary shall
24 take into consideration the benefits and risks for the

1 patient and the least burdensome principles under
2 section 587B(j).

3 “(b) SURVEILLANCE APPROVAL.—

4 “(1) Each developer required to conduct sur-
5 veillance of an in vitro clinical test shall submit,
6 within 30 days of receiving an order from the Sec-
7 retary, a plan for the required surveillance. The Sec-
8 retary, within 60 days of the receipt of such plan,
9 shall determine if the person designated to conduct
10 the surveillance has the appropriate qualifications
11 and experience to undertake such surveillance and if
12 the plan will result in useful data that can reveal un-
13 foreseen adverse events or other information nec-
14 essary to protect the health of patients or the public.

15 “(2) The developer shall commence surveillance
16 under this section not later than 15 months after
17 the day on which the Secretary orders such
18 postmarket surveillance, unless the Secretary deter-
19 mines more time is needed to commence surveillance.

20 “(3) The Secretary may order a prospective
21 surveillance period of up to 3 years. Any determina-
22 tion by the Secretary that a longer period is nec-
23 essary shall be made by mutual agreement between
24 the Secretary and the developer or, if no agreement

1 can be reached, upon the completion of a dispute
2 resolution process pursuant to section 562.

3 **“SEC. 587Z. ELECTRONIC FORMAT FOR SUBMISSIONS.**

4 “(a) IN GENERAL.—All submissions to the Food and
5 Drug Administration with respect to an in vitro clinical
6 test, unless otherwise agreed to by the Secretary, shall—

7 “(1) be made electronically; and

8 “(2) with respect to the information required
9 under sections 587B and 587D, utilize the system
10 described in section 587U.

11 “(b) ELECTRONIC FORMAT.—Beginning on such date
12 as the Secretary specifies in final guidance issued under
13 subsection (c), submissions for in vitro clinical tests, in-
14 cluding recommendations submitted by accredited and rec-
15 ognized persons under section 587Q, and any appeals of
16 action taken by the Secretary with respect to such submis-
17 sions, shall be submitted in such electronic format as spec-
18 ified by the Secretary in such guidance.

19 “(c) REGULATIONS AND GUIDANCE.—The Secretary
20 shall issue regulations and guidance implementing this
21 section, as follows:

22 “(1) Such guidance may provide standards for
23 the electronic submission required under subsection
24 (a) or the submission in electronic format required
25 under subsection (b);

1 “(2) Such regulations may—

2 “(A) set forth criteria for waivers of, or ex-
3 emptions from, the requirements of subsection
4 (a) or (b); and

5 “(B) provide any other information for the
6 efficient implementation and enforcement of
7 this section.

8 **“SEC. 587AA. POSTMARKET REMEDIES.**

9 “(a) SAFETY NOTICE.—

10 “(1) IN GENERAL.—If the Secretary determines
11 that an in vitro clinical test presents an unreason-
12 able risk of substantial harm to the public health,
13 and notification under this subsection is necessary to
14 eliminate the unreasonable risk of such harm and no
15 more practicable means is available under the provi-
16 sions of this Act (other than this section) to elimi-
17 nate the risk, the Secretary may issue such order as
18 may be necessary to ensure that adequate safety no-
19 tice is provided in an appropriate form, by the per-
20 sons and means best suited under the circumstances,
21 to all health care professionals who prescribe, order,
22 or use the in vitro clinical test and to any other per-
23 son (including developers, importers, distributors, re-
24 tailers, and users) who should properly receive such
25 notice.

1 “(2) NOTICE TO INDIVIDUALS.—An order
2 under this subsection shall require that the individ-
3 uals subject to the risk with respect to which the
4 order is to be issued be included in the persons to
5 be notified of the risk unless the Secretary deter-
6 mines that notice to such individuals would present
7 a greater danger to the health of such individuals
8 than no such notice. If the Secretary makes such a
9 determination with respect to such individuals, the
10 order shall require the health care professionals who
11 prescribed, ordered, or used the in vitro clinical test
12 provide notification to the individuals for whom the
13 health professionals prescribed, ordered, or used
14 such test, of the risk presented by such in vitro clin-
15 ical test and of any action which may be taken by
16 or on behalf of such individuals to eliminate or re-
17 duce such risk. Before issuing an order under this
18 subsection, the Secretary shall consult with the per-
19 sons required to give notice under the order.

20 “(b) REPAIR, REPLACEMENT, OR REFUND.—

21 “(1) DETERMINATION AFTER AN INFORMAL
22 HEARING.—

23 “(A) IN GENERAL.—If, after affording op-
24 portunity for an informal hearing, the Secretary
25 determines that—

1 “(i) an in vitro clinical test presents
2 an unreasonable risk of substantial harm
3 to the public health;

4 “(ii) there are reasonable grounds to
5 believe that the in vitro clinical test was
6 not properly developed or manufactured
7 considering the state of the art as it ex-
8 isted at the time of its development;

9 “(iii) there are reasonable grounds to
10 believe that the unreasonable risk was not
11 caused by failure of a person other than a
12 developer, importer, distributor, or retailer
13 of the in vitro clinical test to exercise due
14 care in the installation, maintenance, re-
15 pair, or use of the in vitro clinical test; and

16 “(iv) the notice authorized by sub-
17 section (a) would not by itself be sufficient
18 to eliminate the unreasonable risk and ac-
19 tion described in paragraph (2) of this sub-
20 section is necessary to eliminate such risk,
21 the Secretary may order the developer, im-
22 porter, or any distributor of such in vitro clin-
23 ical test, or any combination of such persons, to
24 submit to him within a reasonable time a plan
25 for taking one or more of the actions described

1 in paragraph (2). An order issued under the
2 preceding sentence which is directed to more
3 than one person shall specify which person may
4 decide which action shall be taken under such
5 plan and the person specified shall be the per-
6 son who the Secretary determines bears the
7 principal, ultimate financial responsibility for
8 action taken under the plan unless the Sec-
9 retary cannot determine who bears such respon-
10 sibility or the Secretary determines that the
11 protection of the public health requires that
12 such decision be made by a person (including a
13 health professional or user of the in vitro clin-
14 ical test) other than the person the Secretary
15 determines bears such responsibility.

16 “(B) SECRETARY APPROVAL OF PLAN.—
17 The Secretary shall approve a plan submitted
18 pursuant to an order issued under subpara-
19 graph (A) unless the Secretary determines
20 (after affording opportunity for an informal
21 hearing) that the action or actions to be taken
22 under the plan or the manner in which such ac-
23 tion or actions are to be taken under the plan
24 will not assure that the unreasonable risk with
25 respect to which such order was issued will be

1 eliminated. If the Secretary disapproves a plan,
2 the Secretary shall order a revised plan to be
3 submitted within a reasonable time. If the Sec-
4 retary determines (after affording opportunity
5 for an informal hearing) that the revised plan
6 is unsatisfactory or if no revised plan or no ini-
7 tial plan has been submitted to the Secretary
8 within the prescribed time, the Secretary shall
9 (i) prescribe a plan to be carried out by the per-
10 son or persons to whom the order issued under
11 subparagraph (A) was directed, or (ii) after af-
12 fording an opportunity for an informal hearing,
13 by order prescribe a plan to be carried out by
14 a person who is a developer, importer, dis-
15 tributor, or retailer of the in vitro clinical test
16 with respect to which the order was issued but
17 to whom the order under subparagraph (A) was
18 not directed.

19 “(2) ACTIONS ON A PLAN.—The actions which
20 may be taken under a plan submitted under an
21 order issued under paragraph (1)(A) are as follows:

22 “(A) To repair the in vitro clinical test so
23 that it does not present the unreasonable risk
24 of substantial harm with respect to which the
25 order under paragraph (1)(A) was issued.

1 “(B) To replace the in vitro clinical test
2 with a like or equivalent test which is in con-
3 formity with all applicable requirements of this
4 Act.

5 “(C) To refund the purchase price of the
6 in vitro clinical test (less a reasonable allowance
7 for use if such in vitro clinical test has been in
8 the possession of the user for one year or more
9 at the time of notice ordered under subsection
10 (a), or at the time the user receives actual no-
11 tice of the unreasonable risk with respect to
12 which the order was issued under paragraph
13 (1)(A), whichever occurs first).

14 “(3) NO CHARGE.—No charge shall be made to
15 any person (other than a developer, importer, dis-
16 tributor or retailer) for using a remedy described in
17 paragraph (2) and provided under an order issued
18 under paragraph (1), and the person subject to the
19 order shall reimburse each person (other than a de-
20 veloper, manufacturer, importer, distributor, or re-
21 tailer) who is entitled to such a remedy for any rea-
22 sonable and foreseeable expenses actually incurred
23 by such person in using such remedy.

24 “(c) REIMBURSEMENT.—An order issued under sub-
25 section (b)(1)(A) with respect to an in vitro clinical test

1 may require any person who is a developer, importer, dis-
2 tributor, or retailer of the in vitro clinical test to reimburse
3 any other person who is a developer, importer, distributor,
4 or retailer of such in vitro clinical test for such other per-
5 son's expenses actually incurred in connection with car-
6 rying out the order if the Secretary determines such reim-
7 bursement is required for the protection of the public
8 health. Any such requirement shall not affect any rights
9 or obligations under any contract to which the person re-
10 ceiving reimbursement or the person making such reim-
11 bursement is a party.

12 “(d) RECALL AUTHORITY.—

13 “(1) IN GENERAL.—If the Secretary finds that
14 there is a reasonable probability that an in vitro
15 clinical test approved under section 587B or offered
16 under a technology certification order under section
17 587D would cause serious, adverse health con-
18 sequences or death, including by the absence, signifi-
19 cant delay, or discontinuation of appropriate medical
20 treatment, the Secretary shall issue an order requir-
21 ing the appropriate person (including the developers,
22 importers, distributors, or retailers of the in vitro
23 clinical test)—

24 “(A) to immediately cease distribution of
25 such in vitro clinical test; and

1 “(B) to immediately notify health profes-
2 sionals and applicable in vitro clinical test user
3 facilities of the order and to instruct such pro-
4 fessionals and facilities to cease use of such in
5 vitro clinical test.

6 “(2) INFORMAL HEARING.—The order issued
7 under paragraph (1)(A), shall provide the person
8 subject to the order with an opportunity for an in-
9 formal hearing, to be held not later than 10 calendar
10 days after the date of the issuance of the order, on
11 the actions required by the order and on whether the
12 order should be amended to require a recall of such
13 in vitro clinical test. If, after providing an oppor-
14 tunity for such a hearing, the Secretary determines
15 that inadequate grounds exist to support the actions
16 required by the order, the Secretary shall vacate the
17 order.

18 “(3) AMENDED ORDER.—

19 “(A) IN GENERAL.—If, after providing an
20 opportunity for an informal hearing under
21 paragraph (2), the Secretary determines that
22 the order should be amended to include a recall
23 of the in vitro clinical test with respect to which
24 the order was issued, the Secretary shall, except
25 as provided in subparagraph (B), amend the

1 order to require a recall. The Secretary shall
2 specify a timetable in which the recall will occur
3 and shall require periodic reports describing the
4 progress of the recall.

5 “(B) REQUIREMENTS.—An amended order
6 under subparagraph (A)—

7 “(i) shall not include recall of the in
8 vitro clinical test from individuals;

9 “(ii) shall not include recall of an in
10 vitro clinical test from test user facilities if
11 the Secretary determines that the risk of
12 recalling such in vitro clinical test from the
13 facilities presents a greater health risk
14 than the health risk of not recalling the in
15 vitro clinical test from use; and

16 “(iii) shall provide for notice to indi-
17 viduals subject to the risks associated with
18 the use of such in vitro clinical test. In
19 providing the notice required by this
20 clause, the Secretary may use the assist-
21 ance of health professionals who pre-
22 scribed, ordered, or used such an in vitro
23 clinical test for individuals.

1 “(4) CLARIFICATION.—The remedy provided by
2 this subsection shall be in addition to remedies pro-
3 vided by subsections (a), (b), and (c).

4 **“SEC. 587BB. APPLICABILITY.**

5 “(a) IN GENERAL.—An in vitro clinical test shall be
6 subject to the requirements of this subchapter, except as
7 otherwise provided in this subchapter.

8 “(b) INTERSTATE COMMERCE.—Any in vitro clinical
9 test that is offered, including by making available for clin-
10 ical use in the United States is deemed to be an act that
11 constitutes introduction into interstate commerce for pur-
12 poses of enforcing the requirements of this Act.

13 “(c) LEAST BURDENSOME REQUIREMENTS.—

14 “(1) IN GENERAL.—In carrying out this sub-
15 chapter, the Secretary shall consider the least bur-
16 densome means necessary to meet the applicable
17 standard, and other regulatory requirements, as de-
18 termined by the Secretary.

19 “(2) NECESSARY DEFINED.—For purposes of
20 paragraph (1) and paragraph (3), the term ‘nec-
21 essary’ means the minimum required information
22 that would support a determination by the Secretary
23 that the application meet the applicable standard or
24 regulatory requirement, as determined by the Sec-
25 retary.

1 “(d) SERVICE OF ORDERS.—Orders of the Secretary
2 under this section with respect to applications under sub-
3 section (a) or (b) of section 587B or supplements under
4 subsection (f) of such section shall be served—

5 “(1) in person by any officer or employee of the
6 Department of Health and Human Services des-
7 ignated by the Secretary; or

8 “(2) by mailing the order by registered mail or
9 certified mail or electronic equivalent addressed to
10 the applicant at the last known address in the
11 records of the Secretary.

12 “(e) LABORATORIES AND BLOOD AND TISSUE ES-
13 TABLISHMENTS.—

14 “(1) RELATION TO LABORATORY CERTIFI-
15 CATION PURSUANT TO SECTION 353 OF THE PUBLIC
16 HEALTH SERVICE ACT.—Nothing in this subchapter
17 shall be construed to modify the authority of the
18 Secretary with respect to laboratories or clinical lab-
19 oratories under section 353 of the Public Health
20 Service Act.

21 “(2) AVOIDING DUPLICATION.—In imple-
22 menting this subchapter, the Secretary shall avoid
23 issuing or enforcing regulations or guidance that are
24 duplicative of regulations or guidance under section
25 353 of the Public Health Service Act.

1 “(3) BLOOD AND TISSUE.—Nothing in this sub-
2 chapter shall be construed to modify the authority of
3 the Secretary with respect to laboratories, establish-
4 ments, or other facilities to the extent they are en-
5 gaged in the propagation, manufacture, or prepara-
6 tion, including filling, labeling, packaging, and stor-
7 age, of blood, blood components, human cells, tis-
8 sues, or tissue products pursuant to any require-
9 ments under this Act or section 351 or 361 of the
10 Public Health Service Act.

11 “(f) PRACTICE OF MEDICINE.—Nothing in this sub-
12 chapter shall be construed to limit or interfere with the
13 authority of a health care practitioner to prescribe or ad-
14 minister any lawfully offered in vitro clinical test for any
15 condition or disease within a legitimate health care practi-
16 tioner-patient relationship pursuant to applicable Federal
17 or State law.

18 “(g) RULES OF CONSTRUCTION.—

19 “(1) SALE, DISTRIBUTION, LABELING.—Noth-
20 ing in this paragraph shall be construed to limit the
21 authority of the Secretary to establish or enforce re-
22 strictions on the sale, distribution, or labeling of an
23 in vitro clinical test under this Act.

24 “(2) PROMOTION OF UNAPPROVED USES.—
25 Nothing in this paragraph shall be construed to alter

1 any prohibition on the promotion of unapproved uses
2 of legally marketed in vitro clinical tests.

3 **“SEC. 587CC. JUDICIAL REVIEW.**

4 “(a) IN GENERAL.—Not later than 30 days after an
5 order issued pursuant to sections 587B or 587D, any per-
6 son adversely affected by such order may file a petition
7 with the United States Court of Appeals for the District
8 of Columbia or for the circuit wherein such person resides
9 or has a principal place of business for judicial review of
10 such order, in accordance with the procedure set forth in
11 section 517(a).

12 “(b) APPLICATION OF PROVISIONS.—Subsections (a)
13 through (e) of section 517 shall apply with respect to a
14 petition under subsection (a) of this section in the same
15 manner such subsections apply to a petition under section
16 517. Subsection (f) of section 517 shall apply to an order
17 issued under section 587B or 587D.”

18 **SEC. 824. ENFORCEMENT AND OTHER PROVISIONS.**

19 (a) PROHIBITED ACTS.—Section 301 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
21 amended by section **[811]**, is further amended—

22 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),
23 (r), and (y), by inserting “in vitro clinical test,”
24 after “device,” each place it appears;

1 (2) in paragraph (g), by inserting after “mis-
2 branded”, “, and the development within any Terri-
3 tory of any in vitro clinical test that is adulterated
4 or misbranded”;

5 (3) in paragraph (y), by inserting “or 587Q”
6 after “section 523” each place it appears;

7 (4) in paragraph (ff), by striking “or device”
8 and inserting “, device, or in vitro clinical test”; and

9 (5) by adding at the end, the following:

10 “(jjj)(1) Forging, counterfeiting, simulating, or false-
11 ly representing, or without proper authority using any
12 mark, stamp, tag, label, or other identification upon any
13 in vitro clinical test or container, packaging, or labeling
14 thereof so as to render such in vitro clinical test a counter-
15 feit in vitro clinical test.

16 “(2) Making, selling, disposing of, or keeping in pos-
17 session, control, or custody, or concealing any punch, die,
18 plate, stone, or other thing designed to print, imprint, or
19 reproduce the trademark, trade name, or other identifying
20 mark or imprint of another or any likeness of any of the
21 foregoing upon any in vitro clinical test or container, pack-
22 aging, or labeling thereof so as to render such in vitro
23 clinical test a counterfeit in vitro clinical test.

24 “(3) The doing of any act which causes an in vitro
25 clinical test to be a counterfeit in vitro clinical test, or

1 the sale or dispensing, or the holding for sale or dis-
2 pensing, of a counterfeit in vitro clinical test.

3 “(kkk)(1) The introduction or delivery for introduc-
4 tion into interstate commerce of an in vitro clinical test
5 in violation of section 587B(a).

6 “(2) The making of a false, fraudulent, or deceptive
7 statement about an in vitro clinical test that is exempt
8 from premarket review under section 587C.

9 “(3) The failure to maintain complete and accurate
10 documentation for an exemption as required under section
11 587C or the failure to provide labeling required under sec-
12 tion 587L.

13 “(4) With respect to an in vitro clinical test, the sub-
14 mission of any report or listing under this Act that is false
15 or misleading in any material respect.

16 “(5) The failure to comply with a condition of ap-
17 proval, or restriction required under an approved applica-
18 tion under section 587B; the failure to perform a risk
19 analysis required by section 587B; the failure to submit
20 an annual update required under **section**
21 **587J(c)(2)(B)**]; or the failure to complete postmarket
22 surveillance as required under section 587Y.

23 “(6) The failure to comply with applicable require-
24 ments to submit an application or report under section
25 587D(e).

1 “(7) The failure to comply with applicable mitigating
2 measures established under section 587E or to submit,
3 maintain, or make available the documentation required
4 under section 587E(b); or the failure to comply with appli-
5 cable performance standards established under section
6 587R.

7 “(8) The failure to register in accordance with section
8 587J, the failure to provide information required under
9 section 587J(b), or the failure to maintain or submit infor-
10 mation required under section 587J(c).

11 “(9) The failure to comply with requirements under
12 section 587M or 587N, the failure to comply with a re-
13 striction required under section 587O, or the failure to
14 comply with labeling and advertising requirements under
15 section 587O(b).

16 “(10) The failure to comply with the requirements
17 of section 587Q.

18 **【“(11) The failure to comply with any requirement**
19 **of section 587S; the failure to furnish any notification, in-**
20 **formation, material, or report required under section**
21 **587S; or the failure to comply with an order issued under**
22 **section 587S.】**

23 “(12) The failure to furnish information requested by
24 the Secretary under 587G(d)(2).”.

1 (b) PENALTIES.—Section 303 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

3 (1) in subsection (b)(8), by inserting “or coun-
4 terfeit in vitro clinical test” after “counterfeit drug”;

5 (2) in subsection (c)—

6 (A) by striking “; or (5)” and inserting “;
7 (5)”; and

8 (B) by inserting before the period at the
9 end the following: “; or (6) for having violated
10 section 301(fff)(2) if such person acted in good
11 faith and had no reason to believe that use of
12 the punch, die, plate, stone, or other thing in-
13 volved would result in an in vitro clinical test
14 being a counterfeit in vitro clinical test, or for
15 having violated section 301(fff)(3) if the person
16 doing the act or causing it to be done acted in
17 good faith and had no reason to believe that the
18 in vitro clinical test was a counterfeit in vitro
19 clinical test”;

20 (3) in subsection (f)(1)—

21 (A) in subparagraph (A)—

22 (i) by inserting “or in vitro clinical
23 tests” after “which relates to devices”;

24 (ii) by inserting “or section
25 587Q(a)(2)” after “section 704(g)”; and

1 (iii) by inserting “or in vitro clinical
2 tests, as applicable” before the period at
3 the end of the second sentence; and

4 (B) in subparagraph (B)(i), by striking “or
5 520(f)” and inserting “, 520(f), 587K, or
6 587M,”.

7 (c) SEIZURE.—Section 304 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

9 (1) in subsection (a)(2)—

10 (A) by striking “, and (E)” and inserting
11 “, (E)”; and

12 (B) by inserting before the period at the
13 end the following: “, and (F) Any in vitro clin-
14 ical test that is a counterfeit in vitro clinical
15 test, (G) Any container, packaging, or labeling
16 of a counterfeit in vitro clinical test, and (H)
17 Any punch, die, plate, stone, labeling, container,
18 or other thing used or designed for use in mak-
19 ing a counterfeit in vitro clinical test”;

20 (2) in subsection (d)(1), by inserting “in vitro
21 clinical test,” after “device,”; and

22 (3) in subsection (g)—

23 (A) in paragraph (1), by inserting “, in
24 vitro clinical test,” after “device” each place it
25 appears; and

1 (B) in paragraph (2)—
2 (i) in subparagraph (A), by inserting
3 “, in vitro clinical test,” after “device”;
4 and
5 (ii) in subparagraph (B), by inserting
6 “or in vitro clinical test” after “device”
7 each place it appears.

8 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
9 PROVAL, AND SUSPENSION.—Section 306 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
11 amended by adding at the end the following:

12 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
13 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
14 REVIEWS.—

15 “(1) IN GENERAL.—If the Secretary finds that
16 a person has been convicted of a felony for a viola-
17 tion of section 301(gg) or 301(jjj)(1), the Secretary
18 shall debar such person from being accredited under
19 section 587Q and from carrying out activities under
20 an agreement described in section 803(b).

21 “(2) DEBARMENT PERIOD.—The Secretary
22 shall debar a person under paragraph (1) for the fol-
23 lowing periods:

24 “(A) The period of debarment of a person
25 (other than an individual) shall not be less than

1 1 year or more than 10 years, but if an act
2 leading to a subsequent debarment under such
3 paragraph occurs within 10 years after such
4 person has been debarred under such para-
5 graph, the period of debarment shall be perma-
6 nent.

7 “(B) The debarment of an individual shall
8 be permanent.

9 “(3) TERMINATION OF DEBARMENT; JUDICIAL
10 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
11 (e), (i), (j), and (l)(1) apply with respect to a person
12 (other than an individual) or an individual who is
13 debarred under paragraph (1) to the same extent
14 and in the same manner as such subsections apply
15 with respect to a person who is debarred under sub-
16 section (a)(1), or an individual who is debarred
17 under subsection (a)(2), respectively.”.

18 (e) EXPANDED ACCESS TO UNAPPROVED THERAPIES
19 AND DIAGNOSTICS.—Section 561 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
21 ed—

22 (1) in subsections (a) through (d)—

23 (A) by striking “or investigational devices”
24 each place it appears and inserting “, investiga-

1 tional devices, or investigational in vitro clinical
2 tests”; and

3 (B) by striking “or investigational device”
4 each place it appears (other than the second
5 such place in paragraph (3)(A)) of subsection
6 (c) and inserting “, investigational device, or
7 investigational in vitro clinical test”;

8 (2) in subsection (b)(4) by striking “or 520(g)”
9 and inserting “, 520(g), or 587S” each place it ap-
10 pears;

11 (3) in subsection (c)—

12 (A) by amending the subsection heading to
13 read: “TREATMENT INVESTIGATIONAL NEW
14 DRUG APPLICATIONS, TREATMENT INVESTIGA-
15 TIONAL DEVICE EXEMPTIONS, AND TREAT-
16 MENT INVESTIGATIONAL IN VITRO CLINICAL
17 TEST EXEMPTIONS.—”;

18 (B) in paragraph (3)(A), by striking “or
19 investigational device exemption in effect under
20 section 520(g)” and inserting “, investigational
21 device exemption in effect under section 520(g),
22 or investigational in vitro clinical test exemption
23 under section 587S”;

24 (C) by striking “or treatment investiga-
25 tional device exemption” each place it appears

1 and inserting “, treatment investigational device
2 exemption, or treatment investigational in vitro
3 clinical test exemption”; and

4 (D) in paragraph (5), by striking “or
5 520(g)” and inserting “, 520(g), or 587S”;

6 (E) in the matter following paragraph (7)
7 by striking “or 520(g)” each place it appears
8 and inserting “, 520(g) or 587S”; and

9 (4) by amending subsection (e) to read as fol-
10 lows:

11 “(e) DEFINITIONS.—In this section, the terms ‘inves-
12 tigational drug’, ‘investigational device’, ‘investigational in
13 vitro clinical test’, ‘treatment investigational new drug ap-
14 plication’, ‘treatment investigational device exemption’,
15 and ‘treatment investigational in vitro clinical test exemp-
16 tion’ shall have the meanings given the terms in regula-
17 tions prescribed by the Secretary.”.

18 (f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
19 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 360bbb–8a(b)) is amended by inserting “an in
21 vitro clinical test, as defined in subsection (ss) of such sec-
22 tion,” before “or a biological product”.

23 (g) PATIENT PARTICIPATION IN MEDICAL PRODUCT
24 DISCUSSION.—The heading of subsection (a) of section
25 569C of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 360bbb–8c) is amended by striking “Drugs and
2 Devices” and inserting “Drugs, Devices, and In Vitro
3 Clinical Tests”.

4 (h) REGULATIONS AND HEARINGS.—Section
5 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting
7 “and in vitro clinical tests” after “devices”.

8 (i) RECORDS.—Section 703 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

10 (1) by inserting “in vitro clinical tests” after
11 “devices” each place such term appears; and

12 (2) by inserting “in vitro clinical test” after
13 “device” each place such term appears.

14 (j) FACTORY INSPECTION.—Section 704 of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
16 than subsection (g)) is amended—

17 (1) by striking “drugs or devices” each place it
18 appears and inserting “drugs, devices, or in vitro
19 clinical tests”;

20 (2) in subsection (a)(1), in the fourth sentence,
21 by striking “or chapter IX” and inserting “section
22 587S, section 587M, section 587N, or chapter IX”;

23 (3) after making the amendments in para-
24 graphs (1) and (2), by inserting “in vitro clinical
25 tests,” after “devices,” each place it appears;

1 (4) in subsection (a)(2)(B)—

2 (A) by inserting “or in vitro clinical tests”
3 after “prescribe or use devices”; and

4 (B) by inserting “or in vitro clinical tests”
5 after “process devices”;

6 (5) by inserting “in vitro clinical test,” after
7 “device,” each place it appears;

8 (6) in subsection (e), by inserting “, or section
9 587M, 587N, or 587S,” after “section 519 or
10 520(g)”;

11 (7) in subsection (f)(3)—

12 (A) in subparagraph (A), by striking “or”
13 at the end;

14 (B) in subparagraph (B), by striking the
15 period at the end and inserting “; or”; and

16 (C) after subparagraph (B), by inserting
17 the following:

18 “(C) is accredited under section 587Q.”

19 (8) by adding at the end the following:

20 “(i) For purposes of this section, the term ‘establish-
21 ment’ includes a laboratory performing an in vitro clinical
22 test.”

23 (k) PUBLICITY.—Section 705(b) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
25 by inserting “in vitro clinical tests,” after “devices,”

1 (l) PRESUMPTION.—Section 709 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
3 inserting “in vitro clinical test,” after “device,”.

4 (m) LISTING AND CERTIFICATION OF COLOR ADDI-
5 TIVES FOR FOODS, DRUGS, AND COSMETICS.—Section
6 721(a) of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 379e(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
9 inserting “or in vitro clinical tests” after “or de-
10 vices”; and

11 (2) in the flush text following paragraph (2)—

12 (A) by inserting “or an in vitro clinical
13 test” after “a device”; and

14 (B) by inserting “or in vitro clinical tests”
15 after “devices”.

16 (n) IMPORTS AND EXPORTS.—Section 801 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
18 is amended—

19 (1) in subsection (a)—

20 (A) by inserting “in vitro clinical tests,”
21 after “devices,” each place it appears; and

22 (B) by inserting “in the case of an in vitro
23 clinical test, the test does not conform to the
24 applicable requirements of section 587K, or”
25 after “requirements of section 520(f), or”;

1 (2) in subsection (d)(3)—

2 (A) in subparagraph (A)—

3 (i) in the matter preceding clause (i),
4 by inserting “and no component of an in
5 vitro clinical test or other article of in vitro
6 clinical test that requires further proc-
7 essing,” after “health-related purposes”;

8 (ii) in clause (i), by striking “drug or
9 device” and inserting “drug, device, or in
10 vitro clinical test”; and

11 (iii) in clause (i)(I), by inserting “in
12 vitro clinical test,” after “device,”; and

13 (B) in subparagraph (B), by inserting “in
14 vitro clinical test,” after “device,”;

15 (3) in subsection (e)(1), by inserting “in vitro
16 clinical test,” after “device,”; and

17 (4) in subsection (o)—

18 (A) by inserting “or in vitro clinical test”
19 after “device”;

20 (B) and “section 587J of each foreign es-
21 tablishment” after “section 510(i) of each es-
22 tablishment”.

23 (o) OFFICE OF INTERNATIONAL RELATIONS.—Sec-
24 tion 803 of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 383) is amended—

1 (1) in subsection (b)—

2 (A) in the matter preceding paragraph (1),
3 by inserting “and in vitro clinical tests” after
4 “devices”; and

5 (B) in paragraph (1), by inserting “quality
6 requirements established under section 587K;
7 and” at the end; and

8 (2) in subsection (c)—

9 (A) in paragraph (2), by inserting “in vitro
10 clinical tests,” after “devices,”; and

11 (B) in paragraph (4), by inserting “or in
12 vitro clinical tests” after “devices”.

13 (p) RECOGNITION OF FOREIGN GOVERNMENT IN-
14 SPECTIONS.—Section 809(a)(1) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-
16 ed by inserting “, or of foreign establishments registered
17 under section 587J” after “510(h)”.

18 (q) FOOD AND DRUG ADMINISTRATION.—Section
19 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 393(b)(2)) is amended—

21 (1) in subparagraph (D), by striking “and” at
22 the end;

23 (2) in subparagraph (E), by striking the semi-
24 colon at the end and inserting “; and”; and

25 (3) by adding at the end the following:

1 “(F) in vitro clinical tests are analytically
2 and clinically valid;”.

3 (F) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 399b(b)) is amended—

6 (1) in paragraph (1), by inserting “in vitro clin-
7 ical tests,” after “devices,”; and

8 (2) in paragraph (4), by striking “and device
9 manufacturers” and inserting “device manufactur-
10 ers, and in vitro clinical test developers,”.

11 (s) COUNTERMEASURE PROVISIONS OF THE PUBLIC
12 HEALTH SERVICE ACT.—Title III of the Public Health
13 Service Act is amended—

14 (1) in section 319F–1(a)(2)(A) (42 U.S.C.
15 247d–6a(a)(2)(A))—

16 (A) in the matter preceding clause (i)—

17 (i) by striking “or device” and insert-
18 ing “device”; and

19 (ii) by inserting “or an in vitro clin-
20 ical tests (as that term is defined in sec-
21 tion 201(ss) of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 321(ss)),”
23 after “Act (21 U.S.C. 321(h)),”; and

1 (B) in each of clauses (ii) and (iii), by
2 striking “or device” and inserting “device, or in
3 vitro clinical test”;

4 (2) in section 319F–2(c)(1)(B) (42 U.S.C.
5 247d–6b(c)(1)(B))—

6 (A) by striking “or device” and inserting
7 “device”; and

8 (B) by inserting “, or an in vitro clinical
9 test (as that term is defined in section 201(ss)
10 of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 321(ss)))” after “Act (21 U.S.C.
12 321(h)),”; and

13 (3) in section 319F–3(i)(7) (42 U.S.C. 247d–
14 6d(i)(7))—

15 (A) in the matter preceding subparagraph
16 (A)—

17 (i) by striking “or device” and insert-
18 ing “device”; and

19 (ii) by inserting “or an in vitro clin-
20 ical tests (as that term is defined in sec-
21 tion 201(ss) of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 321(ss)),”
23 after “Act (21 U.S.C. 321(h))”;

24 (B) in subparagraph (A)—

- 1 (i) by moving the margin of clause
2 (iii) 2 ems to the left; and
3 (ii) in clause (iii), by striking “or de-
4 vice” and inserting “device, or in vitro clin-
5 ical test”; and
6 (C) in subparagraph (B)—
7 (i) in clause (i), by inserting “or the
8 subject of a technology certification order”
9 after “approved or cleared”; and
10 (ii) in clause (ii), by striking “or
11 520(g)” and inserting “, 520(g), or 587S”.

12 **SEC. 825. TRANSITION.**

13 (a) IMPLEMENTATION.—

14 (1) EFFECTIVE DATE.—

15 (A) IN GENERAL.—Except as otherwise
16 provided in this section, the amendments made
17 by this Act shall take effect on October 1, 2027
18 (in this section and in subchapter J of chapter
19 V of the Federal Food, Drug, and Cosmetic
20 Act, as added by this Act, referred to in this
21 section as the “effective date of this Act”).

22 (B) EXCEPTIONS.—

23 (i) IN GENERAL.—The Secretary of
24 Health and Human Services (in this sec-
25 tion referred to as the “Secretary”) may

1 take the actions described in paragraph
2 (3), and may expend such funds as the
3 Secretary determines necessary to ensure
4 an orderly transition, including prior to the
5 effect date of this Act.

6 (ii) IMPLEMENTATION OF CERTAIN
7 PROVISIONS.—The Secretary may imple-
8 ment sections 587J and 587U of the Fed-
9 eral Food, Drug, and Cosmetic Act (as
10 added by section 3) beginning on October
11 1, 2024, and such sections may take effect
12 not earlier than October 1, 2027, to the
13 extent and for the purposes indicated in
14 such sections. In the case of a developer
15 who, between October 1, 2024, and the ef-
16 fective date of this Act specified in sub-
17 paragraph (A), registers under such sec-
18 tion 587K with respect to an article that
19 is an in vitro clinical test, such developer
20 shall not be required to register with re-
21 spect to such article under section 510 of
22 such Act (21 U.S.C. 360).

23 (2) TREATMENT OF ARTICLES BEFORE EFFEC-
24 TIVE DATE.—Until the effective date of this Act, ar-
25 ticles that, upon such effective date, meet the defini-

1 tion of an in vitro clinical test under section 201(ss)
2 of the Federal Food, Drug, and Cosmetic Act (as
3 added by section 2) and that are approved or cleared
4 under section 510(k), 513(f)(2), or 515 of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 360(k); 360c(f)(2); 360e) or for which a humani-
7 tarian device exemption has been granted under sec-
8 tion 520(m) of such Act (21 U.S.C. 360j(m)), shall
9 be considered devices as defined in section 201(h) of
10 such Act (21 U.S.C. 321(h)) and subject to the ap-
11 plicable device requirements under the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
13 seq.).

14 (3) ACTIONS.—The Secretary—

15 (A) shall—

16 (i) within 1 year of the date of enact-
17 ment of this Act, hold the public meetings
18 described in section 587D(c) of the Fed-
19 eral Food, Drug, and Cosmetic Act (as
20 added by section 3);

21 (ii) within 3 years of the date of en-
22 actment of this Act, promulgate final regu-
23 lations required under sections **[xxx]**; and

24 (iii) within 30 months of the date of
25 enactment of this Act, issue final guidance

1 on applicability requirements under section
2 **[xxx]**; and

3 (B) may take additional actions after the
4 date of enactment that the Secretary deter-
5 mines necessary to ensure an orderly transition,
6 which may not take effect until after the effec-
7 tive date, including—

8 (i) establishment of mitigating meas-
9 ures for an in vitro clinical test or category
10 of in vitro clinical tests; and

11 (ii) establishment of the comprehen-
12 sive test information system under section
13 587U.

14 (4) APPLICABILITY OF GUIDANCE AND REGULA-
15 TIONS.—Notwithstanding the date on which guid-
16 ance or regulations are issued under paragraph (3)
17 and section 587K, no guidance or regulations issued
18 pursuant to the amendments made by this Act shall
19 be implemented or take effect until the effective date
20 of this Act, as described in paragraph (1), except as
21 otherwise specified in this Act (including the amend-
22 ments made by this Act).

23 (b) APPLICATION OF AUTHORITIES TO IN VITRO
24 CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE
25 DATE OF THIS ACT.—For any in vitro clinical test, as

1 defined in section 201(ss) of the Federal Food, Drug, and
2 Cosmetic Act, as added by section 823, for which a sub-
3 mission for approval under section 515 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360e), clear-
5 ance under section 510(k) of such Act (21 U.S.C. 360(k)),
6 authorization under section 513(f)(2) of such Act (21
7 U.S.C. 360c(f)(2)), or licensure under section 351 of the
8 Public Health Service Act (42 U.S.C. 262) is pending on
9 the effective date of this Act, including transitional in vitro
10 clinical tests as described in subsection (c), the Secretary
11 may review and take action on such submission after the
12 effective date of this Act according to the statutory provi-
13 sion under which such submission was submitted.

14 (c) APPLICATION OF AUTHORITIES TO TRANSI-
15 TIONAL IN VITRO CLINICAL TESTS.—

16 (1) DEFINITION.—For purposes of this section,
17 the term “transitional in vitro clinical test” means
18 an in vitro clinical test, as defined in section 201(ss)
19 of the Federal Food, Drug, and Cosmetic Act, as
20 added by this Act, that—

21 (A) is first offered for clinical use during
22 the period beginning on the date of enactment
23 of this Act and ending on the effective date of
24 this Act;

1 (B) is developed by a clinical laboratory
2 certified by the Secretary under section 353 of
3 the Public Health Service Act (42 U.S.C. 263a)
4 that meets the requirements for performing
5 high-complexity testing and performed—

6 (i) in the same clinical laboratory in
7 which the test was developed and for which
8 a certification is still in effect under such
9 section 353 that meets the requirements to
10 perform tests of high complexity;

11 (ii) by another laboratory for which a
12 certificate is in effect under such section
13 353 that meets the requirements to per-
14 form tests of high complexity, is within the
15 same corporate organization, and has com-
16 mon ownership by the same parent cor-
17 poration as the laboratory in which the
18 test was developed; or

19 (iii) in the case of a test that was de-
20 veloped by the Centers for Disease Control
21 and Prevention or another laboratory a
22 public health laboratory network coordi-
23 nated or managed by the Centers for Dis-
24 ease Control and Prevention, by a clinical
25 laboratory for which a certificate is in ef-

1 fect under section 353 of such Act that
2 meets the requirements to perform tests of
3 high complexity, and that is within a pub-
4 lic health laboratory network coordinated
5 or managed by the Centers for Disease
6 Control and Prevention;

7 (C) when first offered, is not approved
8 under section 515 of the Federal Food, Drug,
9 and Cosmetic Act, cleared under section 510(k)
10 of such Act, authorized under section 513(f)(2)
11 of such Act, subject to a humanitarian device
12 exemption under section 520(m) of such Act
13 (21 U.S.C. 360j(m)), subject to an exemption
14 for investigation use under section 520(g) of
15 such Act (21 U.S.C. 360j(g)), authorized under
16 section 564 of such Act (21 U.S.C. 360bbb-3),
17 or licensed under section 351 of the Public
18 Health Service Act (42 U.S.C. 262).

19 (2) **PREMARKET REVIEW OR TECHNOLOGY CER-**
20 **TIFICATION.**—A transitional in vitro clinical test
21 may be offered after the effective date of this Act,
22 subject to applicable requirements of the Federal
23 Food, Drug, and Cosmetic Act or Public Health
24 Service Act other than subchapter J of chapter V of

1 the Federal Food, Drug, and Cosmetic Act, as
2 added by section 823—

3 (A) if the in vitro clinical test is exempt
4 under section 587C of the Federal Food, Drug,
5 and Cosmetic Act from premarket review; or

6 (B) if the in vitro clinical test is not so ex-
7 empt, until completion of the Secretary's review
8 of a submission—

9 (i) for approval under section 515 of
10 the Federal Food, Drug, and Cosmetic
11 Act, cleared under section 510(k) of such
12 Act, authorization under section 513(f)(2)
13 of such Act, for a humanitarian device ex-
14 emption under section 520(m) of such Act
15 (21 U.S.C. 360j(m)), for an exemption for
16 investigation use under section 520(g) of
17 such Act (21 U.S.C. 360j(g)), authoriza-
18 tion under section 564 of such Act (21
19 U.S.C. 360bbb-3), or approval under sec-
20 tion 351 of the Public Health Service Act
21 (42 U.S.C. 201 et seq.), pursuant to sub-
22 section (b); or

23 (ii) under section 587B or 587D of
24 the Federal Food, Drug, and Cosmetic
25 Act, as added by this Act.

1 (d) CONVERSION.—

2 (1) DEEMED PREMARKET APPROVAL.—Begin-
3 ning on the effective date of this Act—

4 (A) any in vitro clinical test (as defined in
5 section 201(ss) of the Federal Food, Drug, and
6 Cosmetic Act, as added by section 2) with a
7 premarket approval under section 515 of the
8 Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360e) or a licensure under section 351
10 of the Public Health Service Act (42 U.S.C.
11 262) is deemed to be approved pursuant to an
12 application under section 587B(e) of the Fed-
13 eral Food, Drug, and Cosmetic Act, as added
14 by this Act; and

15 (B) any in vitro clinical test (as so defined)
16 that was cleared under section 510(k) of the
17 Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 360(k)) or authorized under section
19 513(f)(2) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 360c(f)(2)) is deemed to
21 be approved pursuant to an application under
22 section 587B(d) of the Federal Food, Drug,
23 and Cosmetic Act, as added by this Act.

24 **[(2) DEEMED INVESTIGATIONAL USE EXEMP-**
25 **TION.—**Any in vitro clinical test (as defined in sec-

1 tion 201(ss) of the Federal Food, Drug, and Cos-
2 metic Act, as added by section 2) that has an inves-
3 tigational device exemption in effect under section
4 520(g) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 360j(g)) is deemed to have an investiga-
6 tional use exemption in effect under section 587S of
7 such Act, as added by this Act, beginning on the ef-
8 fective date of this Act. *Coordinate this paragraph*
9 *and paragraph (3) with subsection (b).】*

10 【(3) DEEMED HUMANITARIAN DEVICE EXEMP-
11 TION.—Any in vitro clinical test (as defined in sec-
12 tion 201(ss) of the Federal Food, Drug, and Cos-
13 metic Act, as added by section 2) that has an ap-
14 proved humanitarian device exemption under section
15 520(m) of such Act is deemed to have a humani-
16 tarian test exemption under section 587A(g) of such
17 Act, as added by this Act, beginning on the effective
18 date of this Act.】

19 (4) DEEMED DESIGNATED BREAKTHROUGH.—
20 Any in vitro clinical test (as defined in section
21 201(gg) of the Federal Food, Drug, and Cosmetic
22 Act, as added by section 2) that has received a
23 breakthrough device designation under section
24 515B(e)(1)(D) of such Act (21 U.S.C. 360e-
25 3(e)(1)(D)) is deemed to have a breakthrough in

1 vitro clinical test designation under section 587C of
2 such Act, as added by this Act, beginning on the ef-
3 fective date of this Act.

4 (5) DEEMED REQUEST FOR INFORMAL FEED-
5 BACK.—With regard to any in vitro clinical test that
6 is the subject of a pre-submission request described
7 in the guidance, “Requests for Feedback and Meet-
8 ings for Medical Device Submissions: The Q-Submis-
9 sion Program”, issued by the Food and Drug Ad-
10 ministration on January 6, 2021, such request is
11 deemed to constitute a request for informal feedback
12 under section 587F of the Federal Food, Drug, and
13 Cosmetic Act, as added by section 3, beginning on
14 the effective date of this Act.

15 (e) PREVIOUSLY CLASSIFIED DEVICES.—Notwith-
16 standing section 587 of the Federal Food, Drug, and Cos-
17 metic Act, as added by section 823, for purposes of sub-
18 chapter J of chapter V of such Act, as added by section
19 823, the following apply:

20 (1) In the case of an in vitro clinical test type
21 that has been classified by the Secretary as a class
22 I device pursuant to section 513 of such Act (21
23 U.S.C. 360c), such in vitro clinical test shall be low-
24 risk, unless reclassified by the Secretary pursuant to
25 section 587F of such Act.

1 (2) In the case of an in vitro clinical test type
2 that has been classified by the Secretary as a class
3 II device pursuant to section 513 of such Act (21
4 U.S.C. 360c), such in vitro clinical test shall be
5 moderate-risk, unless reclassified by the Secretary
6 pursuant to section 587F of such Act.

7 (3) In the case of an in vitro clinical test type
8 that has been classified by the Secretary as a class
9 III device pursuant to section 513 of such Act (21
10 U.S.C. 360c), such in vitro clinical test shall be
11 high-risk, unless reclassified by the Secretary pursu-
12 ant to section 587F of such Act.

13 **SEC. 826. EMERGENCY USE AUTHORIZATION.**

14 (a) IN GENERAL.—Section 564 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-
16 ed—

17 (1) in subsection (a)—

18 (A) in paragraphs (1) and (4)(C), by in-
19 serting “in vitro clinical test,” before “or bio-
20 logical product” each place such term appears;
21 and

22 (B) in paragraph (2)(A), by striking “or
23 515” and inserting “515, or 587B”;

24 (2) in subsection (e)—

25 (A) in paragraph (3)—

1 (i) in subparagraph (B), by striking
2 “and” at the end;

3 (ii) in subparagraph (C), by striking
4 the period and inserting “; and”; and

5 (iii) by adding at the end the fol-
6 lowing:

7 “(D) quality requirements (with respect to
8 in vitro clinical tests) under section 587K.”;
9 and

10 (B) in paragraph (4)—

11 (i) in subparagraph (A), by striking “;
12 or” and inserting a semicolon;

13 (ii) in subparagraph (B), by striking
14 the period and inserting “; or”; and

15 (iii) by adding at the end the fol-
16 lowing:

17 “(C) with respect to in vitro clinical tests,
18 requirements applicable to restricted in vitro
19 clinical tests pursuant to section 587O.”;

20 (3) in subsection (m)—

21 (A) in the subsection heading, by striking
22 “LABORATORY TESTS ASSOCIATED WITH DE-
23 VICES” inserting “IN VITRO CLINICAL TESTS”
24 after “DEVICES”; and

25 (B) in paragraph (1)—

1 (i) by striking “to a device” and in-
2 serting “to an in vitro clinical test”;

3 (ii) by striking “such device” and in-
4 serting “such in vitro clinical test”.

5 (b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
6 tion 564A(a)(2) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 360bbb–3a(a)(2)) is amended by inserting
8 “in vitro clinical test,” after “device,”.

9 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
10 tion 564B(2) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bbb–3b(2)) is amended—

12 (1) in subparagraph (A), by striking “or 515”
13 and inserting “515, or 587B”; and

14 (2) in subparagraph (B), by striking “or 520”
15 and inserting 520, or 587S.

16 **SEC. 827. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

17 Section 511A of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 360a–2) is amended—

19 (1) in subsection (a)(1)(C)—

20 (A) by striking “clear under section
21 510(k), classify under section 513(f)(2), or ap-
22 prove under section 515” and inserting “ap-
23 prove under section 587B, exempt from pre-
24 market review under section 587C, or grant a

1 technology certification order under section
2 587D”; and

3 (B) by striking “testing devices” and in-
4 sserting “in vitro clinical tests”;

5 (2) in subsection (c)(5), by striking “drug or
6 device” each place it appears and inserting “drug,
7 device, or in vitro clinical test”;

8 (3) in subsection (e)—

9 (A) in the heading, by striking “TESTING
10 DEVICES” and inserting “IN VITRO CLINICAL
11 TESTS”;

12 (B) in paragraph (1)—

13 (i) by striking “510, 513, and 515,”
14 and inserting “587B, and 587D”;

15 (ii) by striking “antimicrobial suscep-
16 tibility testing device” and inserting “anti-
17 microbial susceptibility in vitro clinical
18 test”; and

19 (iii) by striking “such device” and in-
20 sserting “such in vitro clinical test”;

21 (C) in paragraph (2)—

22 (i) in the heading, by striking “TEST-
23 ING DEVICES” and inserting “IN VITRO
24 CLINICAL TESTS”;

1 (ii) in subparagraphs (A) and (B)
2 (other than clause (iii) of such subpara-
3 graph (B)), by striking “device” each place
4 it appears and inserting “in vitro clinical
5 test”; and

6 (iii) in subparagraph (B)(iii), by strik-
7 ing “a device” and inserting “an in vitro
8 clinical test”; and

9 (iv) by amending subparagraph (C) to
10 read as follows:

11 “(C) The antimicrobial susceptibility in
12 vitro clinical test meets all other requirements
13 to be approved under section 587B, exempted
14 from premarket review under section 587C, or
15 offered under a technology certification order
16 under section 587D.”; and

17 (4) in subsection (f), by amending paragraph
18 (1) to read as follows:

19 “(1) The term ‘antimicrobial susceptibility in
20 vitro clinical test’ means an in vitro clinical test that
21 utilizes susceptibility test interpretive criteria to de-
22 termine and report the in vitro susceptibility of cer-
23 tain microorganisms to a drug (or drugs).”; and

24 (5) in subsection (g)(2)—

1 (A) by amending the matter preceding sub-
2 paragraph (A) to read as follows:

3 “(2) with respect to approving an application
4 under section 587B or granting a technology certifi-
5 cation order under section 587D—”; and

6 (B) in subparagraph (A)—

7 (i) by striking “device” and inserting
8 “in vitro clinical test”; and

9 (ii) by striking “antimicrobial suscep-
10 tibility testing device” and inserting “anti-
11 microbial susceptibility in vitro clinical
12 test”.

13 **SEC. 828. COMBINATION PRODUCTS.**

14 (a) IN GENERAL.—Section 503(g) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is
16 amended—

17 (1) in paragraph (1)—

18 (A) in subparagraph (A), by striking “or
19 biological product” and inserting “in vitro clin-
20 ical test, or biological product (except for a
21 product constituted of a device and an in vitro
22 clinical test)”; and

23 (B) in subparagraph (B), by adding at the
24 end the following: “For purposes of this Act, a
25 product that constitutes a combination of a

1 drug and an in vitro clinical test is not a com-
2 bination product within the meaning of this
3 subsection.”; and

4 (C) in subparagraph (D)(ii)—

5 (i) by inserting “or in vitro clinical
6 test” after “device”; and

7 (ii) by inserting “and in vitro clinical
8 tests” before “shall”;

9 (2) in paragraph (3), by striking “safety and
10 effectiveness or substantial equivalence” and insert-
11 ing “safety and effectiveness, substantial equiva-
12 lence, or analytical validity and clinical validity” be-
13 fore “for the approved constituent part”;

14 (3) in paragraph (4)—

15 (A) in subparagraph (A), by striking “or
16 513(f)(2) (submitted in accordance with para-
17 graph (5))” and inserting “513(f)(2) (sub-
18 mitted in accordance with paragraph (5)),
19 587B, or 587D, or an exempt test under sec-
20 tion 587C, as applicable”; and

21 (B) in subparagraph (B), by inserting “,
22 587B, or 587D” after “section 515”;

23 (4) in paragraph (5)(A), by striking “or
24 510(k)” and inserting “, 510(k), 587B, or 587D”;

1 (5) in paragraph (7), by striking “or substan-
2 tial equivalence” and inserting “, substantial equiva-
3 lence, or analytical validity and clinical validity”;

4 (6) in paragraph (8), by adding at the end the
5 following:

6 “(I) This paragraph shall not apply to a
7 combination product constituted of a device and
8 an in vitro clinical test.”; and

9 (7) in paragraph (9)—

10 (A) in subparagraph (C)(i), by striking “or
11 520(g)” and inserting “520(g), 587B, or
12 587D”; and

13 (B) in subparagraph (D), by striking “or
14 520” and inserting “520, 587B, or 587D”.

15 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360bbb–2) is amended by adding at the end the following:

18 “(d) EXEMPTION.—This section shall not apply to a
19 product constituted of a device and an in vitro clinical
20 test.”.

21 **[SEC. 829. RESOURCES.**

22 **[(a) FINDINGS.—**Congress finds that the fees au-
23 thorized by this section will be dedicated to meeting the
24 goals identified in the letters from the Secretary of Health
25 and Human Services to the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives, as set forth in the Congressional Record.】

4 【(b) ESTABLISHMENT OF USER FEE PROGRAM.—】

5 【(1) DEVELOPMENT OF USER FEES FOR IN
6 VITRO CLINICAL TESTS.—

7 【(A) IN GENERAL.—Beginning not later
8 than October 1, 2021, the Secretary of Health
9 and Human Services (in this section referred to
10 as the “Secretary”) shall develop recommenda-
11 tions to present to Congress with respect to the
12 goals, and plans for meeting the goals, for the
13 process of the review of in vitro clinical test ap-
14 plications submitted under subchapter J of
15 chapter V of the Federal Food, Drug, and Cos-
16 metic Act, as added by this Act, for the first 5
17 fiscal years after fiscal year 2022. In developing
18 such recommendations, the Secretary shall con-
19 sult with—】

20 【(i) the Committee on Energy and
21 Commerce of the House of Representa-
22 tives;】

23 【(ii) the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Sen-
25 ate;】

1 **[(iii) scientific and academic experts;]**

2 **[(iv) health care professionals;]**

3 **[(v) representatives of patient and**
4 **consumer advocacy groups; and]**

5 **[(vi) the regulated industry.]**

6 **[(B) PRIOR PUBLIC INPUT.—Prior to be-**
7 **ginning negotiations with the regulated industry**
8 **on the authorization of such subchapter J, the**
9 **Secretary shall—]**

10 **[(i) publish a notice in the Federal**
11 **Register requesting public input on the au-**
12 **thorization of user fees;]**

13 **[(ii) hold a public meeting at which**
14 **the public may present its views on the au-**
15 **thorization, including specific suggestions**
16 **for the recommendations submitted under**
17 **subparagraph (E);]**

18 **[(iii) provide a period of 30 days after**
19 **the public meeting to obtain written com-**
20 **ments from the public suggesting changes**
21 **to such subchapter J; and]**

22 **[(iv) publish any comments received**
23 **under clause (iii) on the website of the**
24 **Food and Drug Administration.]**

1 **[(C) PERIODIC CONSULTATION.—**Not less
2 frequently than once every month during nego-
3 tiations with the regulated industry, the Sec-
4 retary shall hold discussions with representa-
5 tives of patient and consumer advocacy groups
6 to continue discussions of the authorization
7 under such subchapter J and to solicit sugges-
8 tions to be included in the recommendations
9 transmitted to Congress under subparagraph
10 **(E).]**

11 **[(D) PUBLIC REVIEW OF RECOMMENDA-**
12 **TIONS.—**After negotiations with the regulated
13 industry, the Secretary shall—**]**

14 **[(i)** present the recommendations de-
15 veloped under subparagraph (A) to the
16 Committee on Health, Education, Labor,
17 and Pensions of the Senate and the Com-
18 mittee on Energy and Commerce of the
19 House of Representatives;**]**

20 **[(ii)** publish such recommendations in
21 the Federal Register;**]**

22 **[(iii)** provide for a period of 30 days
23 for the public to provide written comments
24 on such recommendations;**]**

1 **[(iv) hold a meeting at which the pub-**
2 **lie may present its views on such rec-**
3 **ommendations; and]**

4 **[(v) after consideration of such public**
5 **views and comments, revise such rec-**
6 **ommendations as necessary.]**

7 **[(E) TRANSMITTAL OF RECOMMENDA-**
8 **TIONS.—**

9 **[(i) IN GENERAL.—Not later than**
10 **June 1, 2021, the Secretary shall transmit**
11 **to Congress the revised recommendations**
12 **under subparagraph (A), a summary of the**
13 **views and comments received under such**
14 **subparagraph, and any changes made to**
15 **the recommendations in response to such**
16 **views and comments.]**

17 **[(ii) RECOMMENDATION REQUIRE-**
18 **MENTS.—The recommendations trans-**
19 **mitted under this subparagraph shall—]**

20 **[(I) include the number of full-**
21 **time equivalent employees per fiscal**
22 **year that are agreed to be hired to**
23 **carry out the goals included in such**
24 **recommendations for each year of the**
25 **5-year period;]**

1 【(II) provide that the amount of
2 operating reserve balance in the user
3 fee program established under this
4 section is not more than the equiva-
5 lent of 10 weeks of operating re-
6 serve;】

7 【(III) require the development of
8 a strategic plan for any surplus within
9 the operating reserve account above
10 the 10-week operating reserve within
11 2 years of the establishment of the
12 program;】

13 【(IV) include an operating re-
14 serve adjustment such that, if the
15 Secretary has an operating reserve
16 balance in excess of 10 weeks of such
17 operating reserves, the Secretary shall
18 decrease such fee revenue and fees to
19 provide for not more than 10 weeks of
20 such operating reserves;】

21 【(V) if an adjustment is made as
22 described in subclause (IV), provide
23 the rationale for the amount of the
24 decrease in fee revenue and fees shall

1 be contained in the Federal Register;
2 and】

3 【(VI) provide that the fees as-
4 sessed and collected for the full-time
5 equivalent employees at the Center for
6 Devices and Radiological Health, with
7 respect to which the majority of time
8 reporting data indicates are dedicated
9 to the review of in vitro clinical tests,
10 are not supported by the funds au-
11 thorized to be collected and assessed
12 under section 738 of the Federal
13 Food, Drug, and Cosmetic Act (21
14 U.S.C. 379j).】

15 【(F) PUBLICATION OF RECOMMENDA-
16 TIONS.—The Secretary shall publish on the
17 website of the Food and Drug Administration
18 the revised recommendations under subpara-
19 graph (A), a summary of the views and com-
20 ments received under subparagraphs (B)
21 through (D), and any changes made to the rec-
22 ommendations originally proposed by the Sec-
23 retary in response to such views and com-
24 ments.】

1 **[(G) MINUTES OF NEGOTIATION MEET-**
2 **INGS.—**

3 **[(i) PUBLIC AVAILABILITY.—**Before
4 transmitting the recommendations devel-
5 oped under subparagraphs (A) through (F)
6 to Congress, the Secretary shall make pub-
7 licly available, on the website of the Food
8 and Drug Administration, minutes of all
9 negotiation meetings conducted under this
10 subsection between the Food and Drug Ad-
11 ministration and the regulated industry.]

12 **[(ii) CONTENT.—**The minutes de-
13 scribed under clause (i) shall summarize
14 any substantive proposal made by any
15 party to the negotiations, any significant
16 controversies or differences of opinion dur-
17 ing the negotiations, and the resolution of
18 any such controversy or difference of opin-
19 ion.]

20 **[(2) ESTABLISHMENT OF USER FEE PRO-**
21 **GRAM.—**Effective on October 1, 2021, provided that
22 the Secretary transmits the recommendations under
23 paragraph (1)(E), the Secretary is authorized to col-
24 lect user fees relating to the submission of in vitro
25 clinical test applications submitted under subchapter

1 J of chapter V of the Federal Food, Drug, and Cos-
2 metic Act, as added by this Act. Fees under such
3 program shall be assessed and collected only if the
4 requirements under paragraph (4) are met.】

5 【(3) AUDIT.—

6 【(A) IN GENERAL.—On the date that is 2
7 years after first receiving a user fee applicable
8 to submission of an in vitro clinical test applica-
9 tion submitted under subchapter J of chapter V
10 of the Federal Food, Drug, and Cosmetic Act,
11 as added by this Act, and on a biennial basis
12 thereafter until October 1, 2027, the Secretary
13 shall perform an audit of the costs of reviewing
14 such applications under such subchapter J.
15 Such an audit shall compare the costs of re-
16 viewing such applications under such sub-
17 chapter J to the amount of the user fee applica-
18 ble to such applications.】

19 【(B) ALTERATION OF USER FEE.—If the
20 audit performed under subparagraph (A) indi-
21 cates that the user fees applicable to applica-
22 tions submitted under such subchapter J exceed
23 30 percent of the costs of reviewing such appli-
24 cations, the Secretary shall alter the user fees
25 applicable to applications submitted under such

1 subchapter J such that the user fees do not ex-
2 ceed such percentage.】

3 【(C) ACCOUNTING STANDARDS.—The Sec-
4 retary shall perform an audit under subpara-
5 graph (A) in conformance with the accounting
6 principles, standards, and requirements pre-
7 scribed by the Comptroller General of the
8 United States under section 3511 of title 31,
9 United States Code, to ensure the validity of
10 any potential variability.】

11 【(4) CONDITIONS.—The user fee program de-
12 scribed in this subsection shall take effect only if the
13 Food and Drug Administration issues draft guidance
14 related to the review requirements for in vitro diag-
15 nostic tests that would be subject to premarket re-
16 view under section 587B of the Federal Food, Drug,
17 and Cosmetic Act, as added by section 3, the review
18 requirements for test categories eligible for tech-
19 nology certification under section 587D of such Act,
20 as added by section 3, and the parameters for the
21 test categories that would be exempt from any re-
22 view under subchapter J of chapter V of such Act.】

23 【(5) USER FEE PROGRAM DEFINITIONS AND
24 RESOURCE REQUIREMENTS.—

1 **[(A) IN GENERAL.—**The term “process for
2 the review of in vitro clinical test applications”
3 means the following activities of the Secretary
4 with respect to the review of premarket applica-
5 tions under section 587B of the Federal Food,
6 Drug, and Cosmetic Act (as added by section
7 3), technology certification applications under
8 section 587D of such Act (as added by section
9 3), and supplements for such applications:】

10 **[(i)** The activities necessary for the
11 review of premarket applications, pre-
12 market reports, and supplements to such
13 applications.】

14 **[(ii)** The issuance of action letters
15 that allow the marketing of in vitro clinical
16 tests or which set forth in detail the spe-
17 cific deficiencies in such applications, re-
18 ports, supplements, or submissions and,
19 where appropriate, the actions necessary to
20 place them in condition for approval.】

21 **[(iii)** The inspection of manufacturing
22 establishments and other facilities under-
23 taken as part of the Secretary’s review of
24 pending premarket applications, technology
25 certifications, and supplements.】

1 【(iv) Monitoring of research con-
2 ducted in connection with the review of
3 such applications, supplements, and sub-
4 missions.】

5 【(v) Review of in vitro clinical test ap-
6 plications subject to section 351 of the
7 Public Health Service Act (42 U.S.C.
8 262), investigational new drug applications
9 under section 505(i) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C.
11 355(i)), or investigational test exemptions
12 under section 587A(m) of the Federal
13 Food, Drug, and Cosmetic Act (as added
14 by section 3), and activities conducted in
15 anticipation of the submission of such ap-
16 plications under section 505(i) of the Fed-
17 eral Food, Drug, and Cosmetic Act or in-
18 vestigational use under section 587S of the
19 Federal Food, Drug, and Cosmetic Act (as
20 added by section 3).】

21 【(vi) The development of guidance,
22 policy documents, or regulations to im-
23 prove the process for the review of pre-
24 market applications, technology certifi-
25 cation applications, and supplements.】

1 【(vii) The development of voluntary
2 test methods, consensus standards, or
3 mandatory performance standards in con-
4 nection with the review of such applica-
5 tions, supplements, or submissions and re-
6 lated activities.】

7 【(viii) The provision of technical as-
8 sistance to in vitro clinical test developers
9 in connection with the submission of such
10 applications, reports, supplements, or sub-
11 missions.】

12 【(ix) Any activity undertaken in con-
13 nection with the initial classification or re-
14 classification of an in vitro clinical test in
15 connection with any requirement for ap-
16 proval of an in vitro clinical test.】

17 【(x) Evaluation of postmarket studies
18 required as a condition of an approval of
19 a premarket application of an in vitro clin-
20 ical test.】

21 【(xi) Compiling, developing, and re-
22 viewing information on relevant in vitro
23 clinical tests to identify issues with the ap-
24 plicable standard for premarket applica-

1 tions, technology certification applications,
2 and supplements.】

3 【(B) RESOURCE REQUIREMENTS.—Fees
4 collected and assessed under this section shall
5 be used for the process for the review of in vitro
6 clinical test applications, as described in sub-
7 paragraph (A), and shall—】

8 【(i) be subject to the limitation under
9 section 738(g)(3) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C.
11 379j(g)(3)), in the same manner that fees
12 collected and assessed under section
13 737(9)(C) of such Act (21 U.S.C.
14 379i(9)(C)) are subject to such limita-
15 tion;】

16 【(ii) include travel expenses for offi-
17 cers and employees of the Food and Drug
18 Administration only if the Secretary deter-
19 mines that such travel is directly related to
20 an activity described in subparagraph (A);
21 and】

22 【(iii) not be allocated to purposes de-
23 scribed under section 722(a) of the Con-
24 solidated Appropriations Act, 2018 (Public
25 Law 115–141).】

1 **[(c) REPORTS.—]**

2 **[(1) PERFORMANCE REPORT.—]**

3 **[(A) IN GENERAL.—]**

4 **[(i) GENERAL REQUIREMENTS.—]** Be-
5 ginning with fiscal year 2021, for each fis-
6 cal year for which fees are collected under
7 this section, the Secretary shall prepare
8 and submit to the Committee on Health,
9 Education, Labor, and Pensions of the
10 Senate and the Committee on Energy and
11 Commerce of the House of Representatives
12 annual reports concerning the progress of
13 the Food and Drug Administration in
14 achieving the goals identified in the rec-
15 ommendations transmitted to Congress by
16 the Secretary pursuant to subsection
17 (b)(1)(E) during such fiscal year and the
18 future plans of the Food and Drug Admin-
19 istration for meeting the goals.】

20 **[(ii) ADDITIONAL INFORMATION.—]**

21 Beginning with fiscal year 2021, the an-
22 nual report under this subparagraph shall
23 include the progress of the Food and Drug
24 Administration in achieving the goals, and

1 future plans for meeting the goals, includ-
2 ing—】

3 【(I) the number of premarket
4 applications filed under section 587B
5 of the Federal Food, Drug, and Cos-
6 metic Act during the applicable fiscal
7 year;】

8 【(II) the number of technology
9 certification applications submitted
10 under section 587D of the Federal
11 Food, Drug, and Cosmetic Act during
12 the applicable fiscal year for each re-
13 view division; and】

14 【(III) the number of break-
15 through designations under section
16 587I of the Federal Food, Drug, and
17 Cosmetic Act during the applicable
18 fiscal year.】

19 【(iii) REAL-TIME REPORTING.—

20 【(I) IN GENERAL.—Not later
21 than 30 calendar days after the end of
22 the second quarter of fiscal year
23 2021, and not later than 30 calendar
24 days after the end of each quarter of
25 each fiscal year thereafter, the Sec-

1 retary shall post the data described in
2 subclause (II) on the website of the
3 Food and Drug Administration for
4 such quarter and on a cumulative
5 basis for such fiscal year, and may re-
6 move duplicative data from the annual
7 report under this subparagraph.】

8 【(II) DATA.—The Secretary
9 shall post the following data in ac-
10 cordance with subclause (I):】

11 【(aa) The number and titles
12 of draft and final guidance on
13 topics related to the process for
14 the review of in vitro clinical
15 tests, and whether such guid-
16 ances were issued as required by
17 statute or pursuant to the rec-
18 ommendations transmitted to
19 Congress by the Secretary pursu-
20 ant to subsection (b)(1)(E).】

21 【(bb) The number and titles
22 of public meetings held on topics
23 related to the process for the re-
24 view of in vitro clinical tests, and
25 if such meetings were required by

1 statute or pursuant to the rec-
2 ommendations transmitted to
3 Congress by the Secretary pursu-
4 ant to subsection (b)(1)(E).】

5 【(iv) RATIONALE FOR IVCT USER FEE
6 PROGRAM CHANGES.—Beginning with fis-
7 cal year 2022, the Secretary shall include
8 in the annual performance report under
9 paragraph (1)—】

10 【(I) data, analysis, and discus-
11 sion of the changes in the number of
12 full-time equivalents hired as agreed
13 upon in the recommendations trans-
14 mitted to Congress by the Secretary
15 pursuant to subsection (b)(1)(E) and
16 the number of full-time equivalents
17 funded by budget authority at the
18 Food and Drug Administration by
19 each division within the Center for
20 Devices and Radiological Health, the
21 Center for Biologics Evaluation and
22 Research, the Office of Regulatory Af-
23 fairs, and the Office of the Commis-
24 sioner;】

1 **[(II)** data, analysis, and discus-
2 sion of the changes in the fee revenue
3 amounts and costs for the process for
4 the review of in vitro clinical tests, in-
5 cluding identifying drivers of such
6 changes; and**]**

7 **[(III)** for each of the Center for
8 Devices and Radiological Health, the
9 Center for Biologics Evaluation and
10 Research, the Office of Regulatory Af-
11 fairs, and the Office of the Commis-
12 sioner, the number of employees for
13 whom time reporting is required and
14 the number of employees for whom
15 time reporting is not required.**]**

16 **[(v) ANALYSIS.—**For each fiscal year,
17 the Secretary shall include in the report
18 under clause (i) an analysis of the fol-
19 lowing:**]**

20 **[(I)** The difference between the
21 aggregate number of premarket appli-
22 cations filed under section 587B or
23 section 587D of the Federal Food,
24 Drug, and Cosmetic Act and the ag-
25 gregate number of major deficiency

1 letters, not approvable letters, and de-
2 nials for such applications issued by
3 the agency, accounting for—】

4 【(aa) the number of applica-
5 tions filed under each of sections
6 587B and 587D of the Federal
7 Food, Drug, and Cosmetic Act
8 during one fiscal year for which a
9 decision is not scheduled to be
10 made until the following fiscal
11 year; and】

12 【(bb) the aggregate number
13 of applications under each of sec-
14 tions 587B and 587D of the
15 Federal Food, Drug, and Cos-
16 metic Act for each fiscal year
17 that did not meet the goals as
18 identified by the recommenda-
19 tions transmitted to Congress by
20 the Secretary pursuant to sub-
21 section (b)(1)(E).】

22 【(II) Relevant data to determine
23 whether the Center for Devices and
24 Radiological Health has met perform-
25 ance enhancement goals identified by

1 the recommendations transmitted to
2 Congress by the Secretary pursuant to
3 subsection (b)(1)(E).】

4 【(III) The most common causes
5 and trends for external or other cir-
6 cumstances affecting the ability of the
7 Food and Drug Administration to
8 meet review time and performance en-
9 hancement goals identified by the rec-
10 ommendations transmitted to Con-
11 gress by the Secretary pursuant to
12 subsection (b)(1)(E).】

13 【(B) PUBLICATION.—With regard to infor-
14 mation to be reported by the Food and Drug
15 Administration to industry on a quarterly and
16 annual basis pursuant to recommendations
17 transmitted to Congress by the Secretary pur-
18 suant to subsection (b)(1)(E), the Secretary
19 shall make such information publicly available
20 on the website of the Food and Drug Adminis-
21 tration not later than 60 days after the end of
22 each quarter or 120 days after the end of each
23 fiscal year, respectively, to which such informa-
24 tion applies.】

1 **[(C) UPDATES.—**The Secretary shall in-
2 clude in each report under subparagraph (A)
3 information on all previous cohorts for which
4 the Secretary has not given a complete response
5 on all in vitro clinical test premarket applica-
6 tions and technology certification orders and
7 supplements, premarket, and technology certifi-
8 cation notifications in the cohort.]

9 **[(2) CORRECTIVE ACTION REPORT.—**Beginning
10 with fiscal year 2022, for each fiscal year for which
11 fees are collected under this section, the Secretary
12 shall prepare and submit a corrective action report
13 to the Committee on Health, Education, Labor, and
14 Pensions and the Committee on Appropriations of
15 the Senate and the Committee on Energy and Com-
16 merce and the Committee on Appropriations of the
17 House of Representatives. The report shall include
18 the following information, as applicable:]

19 **[(A) GOALS MET.—**For each fiscal year, if
20 the Secretary determines, based on the analysis
21 under paragraph (1)(A)(v), that each of the
22 goals identified by the recommendations trans-
23 mitted to Congress by the Secretary pursuant
24 to subsection (b)(1)(E) for the applicable fiscal
25 year have been met, the corrective action report

1 shall include recommendations on ways in which
2 the Secretary can improve and streamline the in
3 vitro clinical test premarket application and
4 technology certification review process.】

5 【(B) GOALS MISSED.—For each of the
6 goals identified by the letters described in rec-
7 ommendations transmitted to Congress by the
8 Secretary pursuant to subsection (b)(1)(E) for
9 the applicable fiscal year that the Secretary de-
10 termines to not have been met, the corrective
11 action report shall include—】

12 【(i) a justification for such determina-
13 tion;】

14 【(ii) a description of the types of cir-
15 cumstances, in the aggregate, under which
16 applications or reports submitted under
17 sections 587B and 587D of the Federal
18 Food, Drug, and Cosmetic Act missed the
19 review goal times but were approved dur-
20 ing the first cycle review, as applicable;】

21 【(iii) a summary and any trends with
22 regard to the circumstances for which a re-
23 view goal was missed; and】

24 【(iv) the performance enhancement
25 goals that were not achieved during the

1 previous fiscal year and a description of ef-
2 forts the Food and Drug Administration
3 has put in place for the fiscal year in
4 which the report is submitted to improve
5 the ability of such agency to meet each
6 such goal for the such fiscal year.】

7 【(3) FISCAL REPORT.—For fiscal years 2021
8 and annually thereafter, not later than 120 days
9 after the end of each fiscal year during which fees
10 are collected under this subpart, the Secretary shall
11 prepare and submit to the Committee on Health,
12 Education, Labor, and Pensions of the Senate and
13 the Committee on Energy and Commerce of the
14 House of Representatives, a report on the implemen-
15 tation of the authority for such fees during such fis-
16 cal year and the use, by the Food and Drug Admin-
17 istration, of the fees collected during such fiscal year
18 for which the report is made.】

19 【(A) CONTENTS.—Such report shall in-
20 clude expenditures delineated by budget author-
21 ity and user fee dollars related to administra-
22 tive expenses and information technology infra-
23 structure contracts and expenditures.】

24 【(B) OPERATING RESERVE.—Such report
25 shall provide the amount of operating reserve

1 balance available each year, and any planned al-
2 locations or obligations of such balance that is
3 above 10 weeks of operating reserve for the pro-
4 gram.】

5 【(4) PUBLIC AVAILABILITY.—The Secretary
6 shall make the reports required under paragraphs
7 (1) through (3) available to the public on the website
8 of the Food and Drug Administration.】

9 【(5) ENHANCED COMMUNICATION.—

10 【(A) COMMUNICATIONS WITH CON-
11 GRESS.—Each fiscal year, as applicable and re-
12 quested, representatives from the Centers with
13 expertise in the review of in vitro clinical tests
14 shall meet with representatives from the Com-
15 mittee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Committee on En-
17 ergy and Commerce of the House of Represent-
18 atives to report on the contents described in the
19 reports under this section.】

20 【(B) PARTICIPATION IN CONGRESSIONAL
21 HEARING.—Each fiscal year, as applicable and
22 requested, representatives from the Food and
23 Drug Administration shall participate in a pub-
24 lic hearing before the Committee on Health,
25 Education, Labor, and Pensions of the Senate

1 and the Committee on Energy and Commerce
2 of the House of Representatives, to report on
3 the contents described in the reports under this
4 section. Such hearing shall occur not later than
5 120 days after the end of each fiscal year for
6 which fees are collected under this section.】

7 **TITLE IX—OTHER PROVISIONS**

8 **SEC. 901. FACILITIES MANAGEMENT.**

9 (a) PDUFA AUTHORITY.—Section 736(g)(2) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379h(g)(2))—

12 (1) in subparagraph (A)(ii)—

13 (A) by striking “shall be available to de-
14 fray” and inserting the following: “shall be
15 available—

16 “(I) for fiscal year 2023, to de-
17 fray”;

18 (B) by striking the period and inserting “;
19 and”; and

20 (C) by adding at the end the following:

21 “(II) for fiscal year 2024 and
22 each subsequent fiscal year, to defray
23 the costs of the resources allocated for
24 the process for the review of human
25 drug applications (including such

1 costs for an additional number of full-
2 time equivalent positions in the De-
3 partment of Health and Human Serv-
4 ices to be engaged in such process),
5 only if the sum of the amounts allo-
6 cated by the Secretary for such costs,
7 excluding costs paid from fees col-
8 lected under this section, plus other
9 costs for the maintenance, renovation,
10 and repair of facilities and acquisition,
11 maintenance, and repair of fixtures,
12 furniture, and other necessary mate-
13 rials and supplies in connection with
14 the process for the review of human
15 drug applications, is no less than the
16 amount allocated for such costs, ex-
17 cluding any such costs paid from fees
18 collected under this section, for fiscal
19 year 1997, multiplied by the adjust-
20 ment factor.”; and

21 (2) in subparagraph (B), by striking “for the
22 process for the review of human drug applications”
23 and inserting “as described in subclause (I) or (II)
24 of such subparagraph, as applicable”.

1 (b) BSUFA AUTHORITY.—Section 744H(f)(2) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
3 52(f)(2)) is amended—

4 (1) in subparagraph (B)(i)—

5 (A) by striking “available for a fiscal year
6 beginning after fiscal year 2012” and inserting
7 the following: “available—

8 “(I) for fiscal year 2023”;

9 (B) by striking “the fiscal year involved.”
10 and inserting “such fiscal year; and”; and

11 (C) by adding at the end the following:

12 “(II) for fiscal year 2024 and
13 each subsequent fiscal year, to defray
14 the costs of the process for the review
15 of biosimilar biological product appli-
16 cations (including such costs for an
17 additional number of full-time equiva-
18 lent positions in the Department of
19 Health and Human Services to be en-
20 gaged in such process), only if the
21 sum of the amounts allocated by the
22 Secretary for such costs, excluding
23 costs paid from fees collected under
24 this section, plus other costs for the
25 maintenance, renovation, and repair

1 of facilities and acquisition, mainte-
2 nance, and repair of fixtures, fur-
3 niture, and other necessary materials
4 and supplies in connection with the
5 process for the review of biosimilar bi-
6 ological product applications, is no
7 less than \$20,000,000, multiplied by
8 the adjustment factor applicable to
9 the fiscal year involved.”; and

10 (2) in subparagraph (C), by striking “subpara-
11 graph (B) in any fiscal year if the costs described
12 in such subparagraph” and inserting “subparagraph
13 (B)(i) in any fiscal year if the costs allocated as de-
14 scribed in clause (i) or (ii) of such subparagraph, as
15 applicable,”.

16 (c) GDUFA AUTHORITY.—Section 744B of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42)
18 is amended—

19 (1) in subsection (e)(2), by striking
20 “744A(11)(C)” and inserting “744A(12)(C)”;

21 (2) in subsection (i)(2)—

22 (A) in subparagraph (A)(ii)—

23 (i) by striking “available for a fiscal
24 year beginning after fiscal year 2012” and
25 inserting the following: “available—

1 “(I) for fiscal year 2023; and”;

2 (ii) by striking “the fiscal year in-
3 volved.” and inserting “such fiscal year;
4 and”; and

5 (iii) by adding at the end the fol-
6 lowing:

7 “(II) for fiscal year 2024 and
8 each subsequent fiscal year, to defray
9 the costs of human generic drug ac-
10 tivities (including such costs for an
11 additional number of full-time equiva-
12 lent positions in the Department of
13 Health and Human Services to be en-
14 gaged in such activities), only if the
15 sum of the amounts allocated by the
16 Secretary for such costs, excluding
17 costs paid from fees collected under
18 this section, plus other costs for the
19 maintenance, renovation, and repair
20 of facilities and acquisition, mainte-
21 nance, and repair of fixtures, fur-
22 niture, and other necessary materials
23 and supplies in connection with
24 human generic drug activities, is no
25 less than \$97,000,000 multiplied by

1 the adjustment factor defined in sec-
2 tion 744A(3) applicable to the fiscal
3 year involved.”; and

4 (B) in subparagraph (B)—

5 (i) by striking “for human generic ac-
6 tivities” and inserting “as described in
7 subclause (I) or (II) of such subparagraph,
8 as applicable”; and

9 **[(ii) by striking “10 percent” and in-**
10 **serting “**[xx]** percent”.]**

11 (d) MDUFA AUTHORITY.—Section 738 of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is
13 amended—

14 (1) in subsection (h)(2)—

15 (A) in subparagraph (A)(ii)—

16 (i) by striking “shall be available to
17 defray” and inserting the following: “shall
18 be available—

19 “(I) for fiscal year 2023, to de-
20 fray”;

21 (ii) by striking the period and insert-
22 ing “; and”; and

23 (iii) by adding at the end the fol-
24 lowing:

1 “(II) for fiscal year 2024 and
2 each subsequent fiscal year, to defray
3 the costs of the resources allocated for
4 the process for the review of device
5 applications (including such costs for
6 an additional number of full-time
7 equivalent positions in the Depart-
8 ment of Health and Human Services
9 to be engaged in such process), only if
10 the sum of the amounts allocated by
11 the Secretary for such costs, excluding
12 costs paid from fees collected under
13 this section, plus other costs for the
14 maintenance, renovation, and repair
15 of facilities and acquisition, mainte-
16 nance, and repair of fixtures, fur-
17 niture and other necessary materials
18 and supplies in connection with the
19 process for the review of device appli-
20 cations, is no less than the amount al-
21 located for such costs, excluding any
22 such costs paid from fees collected
23 under this section, for fiscal year
24 2009 multiplied by the adjustment
25 factor.”; and

1 (B) in subparagraph (B)(i), in the matter
2 preceding subclause (I), by striking “for the
3 process for the review of device applications”
4 and inserting “as described in subclause (I) or
5 (II) of such subparagraph, as applicable”; and
6 (2) in subsection (g)(3), by striking
7 “737(9)(C)” and inserting “737(10)(C)”.

8 **SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

9 Section 902 of the FDA Reauthorization Act of 2017
10 (Public Law 115–52) is amended, in the matter preceding
11 paragraph (1)—

12 (1) by striking “March 1 of each year” and in-
13 serting “120 days after the end of each fiscal year”;
14 and

15 (2) by striking “previous calendar year” and in-
16 serting “previous fiscal year”.

17 **SEC. 903. USER FEE PROGRAM TRANSPARENCY AND AC-**
18 **COUNTABILITY.**

19 (a) PDUFA.—

20 (1) REAUTHORIZATION; REPORTING REQUIRE-
21 MENTS.—

22 (A) PERFORMANCE REPORT.—Section
23 736B(a) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 379h–2(a)) is amended—

25 (i) in paragraph (1)(B)—

1 (I) in clause (vii), by striking “;
2 and” and inserting a semicolon;

3 (II) in clause (viii), by striking
4 the period and inserting “; and”; and

5 (III) by adding at the end the
6 following:

7 “(ix) the number of investigational
8 new drug applications submitted per fiscal
9 year for each review division.”;

10 (ii) in paragraph (4)—

11 (I) by amending subparagraph
12 (A) to read as follows:

13 “(A) data, analysis, and discussion of the
14 changes in the number of individuals hired as
15 agreed upon in the letters described in section
16 101(b) of the Prescription Drug User Fee
17 Amendments of 2022 and the number of re-
18 maining vacancies, the number of full-time
19 equivalents funded by fees collected pursuant to
20 **[section 736]**, and the number of full-time
21 equivalents funded by budget authority at the
22 Food and Drug Administration by each division
23 within the Center for Drug Evaluation and Re-
24 search, the Center for Biologics Evaluation and

1 Research, the Office of Regulatory Affairs, and
2 the Office of the Commissioner;”;

3 (II) by amending subparagraph
4 (B) to read as follows:

5 “(B) data, analysis, and discussion of the
6 changes in the fee revenue amounts and costs
7 for the process for the review of prescription
8 drugs, including identifying—

9 “(i) drivers of such changes; and

10 “(ii) changes in the average total cost
11 per full-time equivalent in the prescription
12 drug application review program;”;

13 (III) in subparagraph (C), by
14 striking the period and inserting “;
15 and”; and

16 (IV) by adding at the end the fol-
17 lowing:

18 “(D) data, analysis, and discussion of the
19 changes in the average and median full-time
20 equivalent hours required to complete review of
21 prescription drug application types.”; and

22 (iii) in paragraph (5)—

23 (I) by redesignating subpara-
24 graphs (B) and (C) as subparagraphs
25 (C) and (D), respectively; and

1 (II) by inserting after subpara-
2 graph (A) the following:

3 “(B) The difference between the aggregate
4 number of new individuals hired for purposes of
5 prescription drug application review in the ap-
6 plicable fiscal year and the aggregate number of
7 positions funded at the end of such fiscal
8 year.”.

9 (2) REAUTHORIZATION.—Section 736B(f) of
10 the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379h–2(f)) is amended—

12 (A) by redesignating paragraphs (4)
13 through (6) as paragraphs (5) through (7), re-
14 spectively;

15 (B) by inserting after paragraph (3) the
16 following:

17 “(4) UPDATES TO CONGRESS.—The Secretary,
18 in consultation with regulated industry, shall provide
19 regular updates on negotiations on the reauthoriza-
20 tion of this part to the Committee on Health, Edu-
21 cation, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House
23 of Representatives.”; and

24 (C) in paragraph (7), as so redesignated—

25 (i) in subparagraph (A)—

1 (I) by striking “Before pre-
2 senting the recommendations devel-
3 oped under paragraphs (1) through
4 (5) to the Congress, the” and insert-
5 ing “The”; and

6 (II) by inserting “, not later than
7 30 days after each such negotiation
8 meeting” before the period at the end;
9 and

10 (ii) in subparagraph (B), by inserting
11 “, in sufficient detail,” after “shall sum-
12 marize”.

13 (b) MDUFA.—

14 (1) AUTHORITY TO ASSESS AND USE DEVICE
15 FEES.—Section 738(g)(3) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 379j(g)(3)) is
17 amended to read as follows:

18 “(3) LIMITATIONS.—Beginning on October 1,
19 2023, the authorities under section 737(10)(C) shall
20 include only leasing and necessary scientific equip-
21 ment.”.

22 (2) REAUTHORIZATION; REPORTING REQUIRE-
23 MENTS.—

1 (A) REPORTS.—Section 738A(a)(1)(A) of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j-1(a)(1)(A)) is amended—

4 (i) in clause (ii)—

5 (I) in subclause (II), by striking
6 “; and” and inserting a semicolon;

7 (II) in subclause (III), by strik-
8 ing the period and inserting a semi-
9 colon; and

10 (III) by adding at the end the
11 following:

12 “(IV) the number of investiga-
13 tional device exemption application
14 submissions under section 520(g) per
15 fiscal year for each review division;
16 and

17 “(V) the number of breakthrough
18 designations for a fiscal year for each
19 review division.”;

20 (ii) in the first clause (iv) (relating to
21 rationale for MDUFA program changes)—

22 (I) by amending subclause (I) to
23 read as follows:

24 “(I) data, analysis, and discus-
25 sion of the changes in the number of

1 individuals hired as agreed upon in
2 the letters described in section 201(b)
3 of the Medical Device User Fee
4 Amendments of 2022 and the number
5 of remaining vacancies, the number of
6 full-time equivalents funded by fees
7 collected pursuant to **【section 738】**,
8 and the number of full time equiva-
9 lents funded by budget authority at
10 the Food and Drug Administration by
11 each division within the Center for
12 Devices and Radiological Health, the
13 Center for Biologics Evaluation and
14 Research, the Office of Regulatory Af-
15 fairs, and the Office of the Commis-
16 sioner;”;

17 (II) by amending subclause (II)
18 to read as follows:

19 “(II) data, analysis, and discus-
20 sion of the changes in the fee revenue
21 amounts and costs for the process for
22 the review of devices, including identi-
23 fying—

24 “(aa) drivers of such
25 changes; and

1 “(bb) changes in the average
2 total cost per full-time equivalent
3 in the medical device review pro-
4 gram;”;

5 (III) in subclause (III), by strik-
6 ing the period and inserting “; and”;
7 and

8 (IV) by adding at the end the fol-
9 lowing:

10 “(IV) data, analysis, and discus-
11 sion of the changes in the average and
12 median full-time equivalent hours re-
13 quired to complete review of medical
14 device application types.”;

15 (iii) by redesignating the second
16 clause (iv) (relating to analysis) as clause
17 (v); and

18 (iv) in clause (v), as so redesignated—

19 (I) by redesignating subclauses
20 (II) and (III) as subclauses (III) and
21 (IV); and

22 (II) by inserting after subclause
23 (I) the following:

24 “(II) The difference between the
25 aggregate number of new individuals

1 hired for purposes of device review in
2 the applicable fiscal year and the ag-
3 gregate number of positions funded at
4 the end of such fiscal year.”.

5 (3) REAUTHORIZATION.—Section 738A(b) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 379j–1(b)) is amended—

8 (A) by redesignating paragraphs (4)
9 through (6) as paragraphs (5) through (7), re-
10 spectively;

11 (B) by inserting after paragraph (3) the
12 following:

13 “(4) UPDATES TO CONGRESS.—The Secretary,
14 in consultation with regulated industry, shall provide
15 regular updates on negotiations on the reauthoriza-
16 tion of this part to the Committee on Health, Edu-
17 cation, Labor, and Pensions of the Senate and the
18 Committee on Energy and Commerce of the House
19 of Representatives.”; and

20 (C) in paragraph (7), as so redesignated—

21 (i) in subparagraph (A)—

22 (I) by striking “Before pre-
23 senting the recommendations devel-
24 oped under paragraphs (1) through

1 (5) to the Congress, the” and insert-
2 ing “The”; and

3 (II) by inserting “, not later than
4 30 days after each such negotiation
5 meeting” before the period at the end;
6 and

7 (ii) in subparagraph (B), by inserting
8 “, in sufficient detail,” after “shall sum-
9 marize”.

10 (c) GDUFA.—

11 (1) REAUTHORIZATION; REPORTING REQUIRE-
12 MENTS.—

13 (A) PERFORMANCE REPORT.—Section
14 744C(a) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 379j–43(a)) is amended—

16 (i) in paragraph (3)—

17 (I) by amending subparagraph
18 (A) to read as follows:

19 “(A) data, analysis, and discussion of the
20 changes in the number of individuals hired as
21 agreed upon in the letters described in section
22 301(b) of the Generic Drug User Fee Amend-
23 ments of 2022 and the number of remaining va-
24 cancies, the number of full-time equivalents
25 funded by fees collected pursuant to [section

1 744B】, and the number of full time equivalents
2 funded by budget authority at the Food and
3 Drug Administration by each division within
4 the Center for Drug Evaluation and Research,
5 the Center for Biologics Evaluation and Re-
6 search, the Office of Regulatory Affairs, and
7 the Office of the Commissioner;”;

8 (II) by amending subparagraph
9 (B) to read as follows:

10 “(B) data, analysis, and discussion of the
11 changes in the fee revenue amounts and costs
12 for generic drug activities, including—

13 “(i) identifying drivers of such
14 changes; and

15 “(ii) changes in the total average cost
16 per full-time equivalent in the generic drug
17 review program;”;

18 (III) in subparagraph (C), by
19 striking the period at the end and in-
20 serting “; and”; and

21 (IV) by adding at the end the fol-
22 lowing:

23 “(D) data, analysis, and discussion of the
24 changes in the average and median full-time

1 equivalent hours required to complete review of
2 abbreviated new drug application types.”; and

3 (ii) in paragraph (4)—

4 (I) by redesignating subpara-
5 graphs (B) and (C) as subparagraphs
6 (C) and (D), respectively; and

7 (II) by inserting after subpara-
8 graph (A) the following:

9 “(B) The difference between the aggregate
10 number of new individuals hired [for purposes
11 of abbreviated new drug application review] in
12 the applicable fiscal year and the aggregate
13 number of positions funded at the end of such
14 fiscal year.”.

15 (2) REAUTHORIZATION.—Section 744C(f) of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 379j–43(f)) is amended—

18 (A) by redesignating paragraphs (4)
19 through (6) as paragraphs (5) through (7), re-
20 spectively;

21 (B) by inserting after paragraph (3) the
22 following:

23 “(4) UPDATES TO CONGRESS.—The Secretary,
24 in consultation with regulated industry, shall provide
25 regular updates on negotiations on the reauthoriza-

1 tion of this part to the Committee on Health, Edu-
2 cation, Labor, and Pensions of the Senate and the
3 Committee on Energy and Commerce of the House
4 of Representatives.”; and

5 (C) in paragraph (7), as so redesignated—

6 (i) in subparagraph (A)—

7 (I) by striking “Before pre-
8 senting the recommendations devel-
9 oped under paragraphs (1) through
10 (5) to the Congress, the” and insert-
11 ing “The”; and

12 (II) by inserting “, not later than
13 30 days after each such negotiation
14 meeting” before the period at the end;
15 and

16 (ii) in subparagraph (B), by inserting
17 “, in sufficient detail,” after “shall sum-
18 marize”.

19 (d) BSUFA.—

20 (1) REAUTHORIZATION; REPORTING REQUIRE-
21 MENTS.—

22 (A) PERFORMANCE REPORT.—Section
23 744I(a) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 379j–53(a)) is amended—

25 (i) in paragraph (4)—

1 (ii) by amending subparagraph (A) to
2 read as follows:

3 “(A) data, analysis, and discussion of the
4 changes in the number of individuals hired as
5 agreed upon in the letters described in section
6 401(b) of the Biosimilar User Fee Amendments
7 of 2022 and the number of remaining vacan-
8 cies, the number of full-time equivalents funded
9 by fees collected pursuant to [section 744H],
10 and the number of full time equivalents funded
11 by budget authority at the Food and Drug Ad-
12 ministration by each division within the Center
13 for Drug Evaluation and Research, the Center
14 for Biologics Evaluation and Research, the Of-
15 fice of Regulatory Affairs, and the Office of the
16 Commissioner;”;

17 (iii) by amending subparagraph (B) to
18 read as follows:

19 “(B) data, analysis, and discussion of the
20 changes in the fee revenue amounts and costs
21 for the process for the review of biosimilar bio-
22 logical product applications, including identi-
23 fying—

24 “(i) drivers of such changes; and

1 “(ii) changes in the average total cost
2 per full-time equivalent in the biosimilar
3 biological product review program;”;

4 (iv) in subparagraph (C), by striking
5 the period at the end and inserting “;
6 and”; and

7 (v) by adding at the end the following:

8 “(D) data, analysis, and discussion of the
9 changes in the average and median full-time
10 equivalent hours required to complete review of
11 biosimilar biological product application types.”;
12 and

13 (B) in paragraph (5)—

14 (i) by redesignating subparagraphs
15 (B) and (C) as subparagraphs (C) and
16 (D), respectively; and

17 (ii) by inserting after subparagraph
18 (A) the following:

19 “(B) The difference between the aggregate
20 number of new individuals hired [for purposes
21 of biosimilar biological product application re-
22 view] in the applicable fiscal year and the ag-
23 gregate number of positions funded at the end
24 of such fiscal year.”.

1 (2) REAUTHORIZATION.—Section 744I(f) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–53(f)) is amended—

4 (A) by redesignating paragraphs (2) and
5 (3) as paragraphs (5) and (6), respectively;

6 (B) by inserting after paragraph (1) the
7 following:

8 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
9 negotiations with the regulated industry on the reau-
10 thorization of this subpart, the Secretary shall—

11 “(A) publish a notice in the Federal Reg-
12 ister requesting public input on the reauthoriza-
13 tion;

14 “(B) hold a public meeting at which the
15 public may present its views on the reauthoriza-
16 tion;

17 “(C) provide a period of 30 days after the
18 public meeting to obtain written comments from
19 the public suggesting changes to this subpart;
20 and

21 “(D) publish the comments on the Food
22 and Drug Administration’s website.

23 “(3) PERIODIC CONSULTATION.—Not less fre-
24 quently than once every month during negotiations
25 with the regulated industry, the Secretary shall hold

1 discussions with representatives of patient and con-
2 sumer advocacy groups to continue discussions of
3 their views on the reauthorization and their sugges-
4 tions for changes to this subpart as expressed under
5 paragraph (2).

6 “(4) UPDATES TO CONGRESS.—The Secretary,
7 in consultation with regulated industry, shall provide
8 regular updates on negotiations on the reauthoriza-
9 tion of this part to the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate and the
11 Committee on Energy and Commerce of the House
12 of Representatives.”; and

13 (C) by adding at the end the following:

14 “(7) MINUTES OF NEGOTIATION MEETINGS.—

15 “(A) PUBLIC AVAILABILITY.—The Sec-
16 retary shall make publicly available, on the pub-
17 lic website of the Food and Drug Administra-
18 tion, minutes of all negotiation meetings con-
19 ducted under this subsection between the Food
20 and Drug Administration and the regulated in-
21 dustry, not later than 30 days after each such
22 negotiation meeting.

23 “(B) CONTENT.—The minutes described
24 under subparagraph (A) shall summarize, in
25 sufficient detail, any substantive proposal made

1 by any party to the negotiations as well as sig-
2 nificant controversies or differences of opinion
3 during the negotiations and their resolution.”.