

117TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. BURR (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests, and for other purposes.

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 “Verifying Accurate Leading-edge IVCT Development Act
6 of 2021” or the “VALID Act of 2021”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Regulation of in vitro clinical tests.

“SUBCHAPTER J—IN VITRO CLINICAL TESTS

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

- Sec. 4. Enforcement and other provisions.
- Sec. 5. Transition.
- Sec. 6. Emergency use authorization.
- Sec. 7. Antimicrobial susceptibility tests.
- Sec. 8. Combination products.
- Sec. 9. Resources.

1 SEC. 2. 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’—

6 “(A) means a test intended by its developer (as
7 defined in section 587) to be used in the collection,
8 preparation, analysis, or in vitro clinical examination

1 of specimens taken or derived from the human body
2 for the purpose of—

3 “(i) identifying or diagnosing a disease or
4 condition;

5 “(ii) providing information for diagnosing,
6 screening, measuring, detecting, predicting,
7 prognosing, analyzing, or monitoring a disease
8 or condition, including by making a determina-
9 tion of an individual’s state of health; or

10 “(iii) selecting, monitoring, or informing
11 therapy or treatment for a disease or condition;
12 and

13 “(B) may include—

14 “(i) a test protocol or laboratory test pro-
15 tocol;

16 “(ii) an instrument (as defined in section
17 587(11));

18 “(iii) a specimen receptacle;

19 “(iv) software, excluding software that is
20 excluded by section 520(o) from the definition
21 of a device under section 201(h), and excluding
22 modifications that are exempt in accordance
23 with section 587A(1)(2)(A); and

24 “(v) subject to subparagraph (2), a compo-
25 nent or part of a test, a test protocol, an instru-

1 ment, an article, or software described in any of
2 clauses (A) through (D) of such subparagraph,
3 whether alone or in combination, including re-
4 agents, calibrators, and controls.

5 “(2) Notwithstanding subparagraph (1)(v), an article
6 intended to be used as a component or part of an in vitro
7 clinical test described in subparagraph (1) is excluded
8 from the definition in subparagraph (1) if the article con-
9 sists of any of the following:

10 “(A) Blood, blood components, or human cells
11 or tissues, from the time of acquisition, donation, or
12 recovery of such article, including determination of
13 donor eligibility, as applicable, until such time as the
14 article is released as a component or part of an in
15 vitro clinical test by the establishment that collected
16 such article.

17 “(B) An article used for invasive sampling, a
18 needle, or a lancet, except to the extent such article,
19 needle, or lancet is an integral component of an arti-
20 cle for holding, storing, or transporting a specimen.

21 “(C) General purpose laboratory equipment, in-
22 cluding certain pre-analytical equipment, as deter-
23 mined by the Secretary.

1 “(D) An article used solely for personal protec-
2 tion during the administering, conducting, or other-
3 wise performing of test activities.”;

4 (2) by adding at the end of section 201(g) the
5 following:

6 “(3) The term ‘drug’ does not include an in vitro clin-
7 ical test.”; and

8 (3) in section 201(h), by striking “section
9 520(o)” and inserting “section 520(o) or an in vitro
10 clinical test”.

11 (b) EXCLUSION FROM DEFINITION OF BIOLOGICAL
12 PRODUCT.—Section 351(i)(1) of the Public Health Serv-
13 ice Act (42 U.S.C. 262(i)(1)) is amended—

14 (1) by striking “(1) The term ‘biological prod-
15 uct’ means” and inserting “(1)(A) The term ‘biologi-
16 cal product’ means”; and

17 (2) by adding at the end the following:

18 “(B) The term ‘biological product’ does not in-
19 clude an in vitro clinical test as defined in section
20 201(ss) of the Federal Food, Drug, and Cosmetic
21 Act.”.

22 (c) IN VITRO CLINICAL TEST DEFINITION.—In this
23 Act, the term “in vitro clinical test” has the meaning given
24 such term in section 201(ss) of the Federal Food, Drug,
25 and Cosmetic Act, as added by subsection (a).

1 **SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.**

2 The Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 301 et seq.) is amended—

4 (1) by amending the heading of chapter V to
5 read as follows: “**DRUGS, DEVICES, AND IN**
6 **VITRO CLINICAL TESTS**”; and

7 (2) by adding at the end of chapter V the fol-
8 lowing:

9 **“Subchapter J—In Vitro Clinical Tests**

10 **“SEC. 587. DEFINITIONS.**

11 “In this subchapter:

12 “(1) ANALYTICAL VALIDITY.—

13 “(A) The term ‘analytical validity’ means,
14 with respect to an in vitro clinical test, the abil-
15 ity of the in vitro clinical test, to—

16 “(i) sufficiently identify, measure, de-
17 tect, calculate, or analyze one or more
18 analytes, biomarkers, substances, or other
19 targets intended to be identified, measured,
20 detected, calculated, or analyzed by the
21 test; or

22 “(ii) as applicable, assist in such iden-
23 tification, measurement, detection, calcula-
24 tion, or analysis.

25 “(B) For an article for taking or deriving
26 specimens from the human body described in

1 section 201(ss)(1)(B)(iii), the term ‘analytical
2 validity’ means that such article performs as in-
3 tended and will support the analytical validity
4 of an in vitro clinical test with which it is used.

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, except that such term—

9 “(A) with respect to test instruments,
10 means a reasonable assurance of analytical va-
11 lidity; and

12 “(B) with respect to articles for taking or
13 deriving specimens from the human body for
14 purposes described in clause (i) or (ii) of section
15 201(ss)(1)(A) means a reasonable assurance of
16 analytical validity and, where applicable, safety.

17 “(3) CLINICAL USE.—The term ‘clinical use’
18 means the operation, application, or functioning of
19 an in vitro clinical test in connection with human
20 specimens, including patient, consumer, and donor
21 specimens, for the purpose for which it is intended
22 as described in section 201(ss)(1)(A).

23 “(4) CLINICAL VALIDITY.—The term ‘clinical
24 validity’ means the ability of an in vitro clinical test

1 to achieve the purpose for which it is intended as de-
2 scribed in section 201(ss)(1)(A).

3 “(5) CROSS-REFERENCED TEST.—The term
4 ‘cross-referenced test’ means an in vitro clinical test
5 that references in its labeling the name or intended
6 use of another medical product that is not an in
7 vitro clinical test.

8 “(6) DEVELOP.—The term ‘develop’, with re-
9 spect to an in vitro clinical test, means—

10 “(A) designing, validating, producing,
11 manufacturing, remanufacturing, propagating,
12 or assembling an in vitro clinical test;

13 “(B) importing an in vitro clinical test;

14 “(C) modifying an in vitro clinical test ini-
15 tially developed by a different person in a man-
16 ner that—

17 “(i) changes any of the listing ele-
18 ments that define indications for use speci-
19 fied in paragraph (10), performance
20 claims, or, as applicable, the safety of such
21 in vitro clinical test; or

22 “(ii) affects the analytical or clinical
23 validity of the in vitro clinical test as in-
24 tended by the developer; or

1 would otherwise cause serious harm to
2 the public health; or

3 “(II) is potentially likely to result
4 in the absence, significant delay, or
5 discontinuation of life-supporting or
6 life-sustaining medical treatment;

7 “(ii) shall account for the degree to
8 which the technology for the intended use
9 of an in vitro clinical test or tests is well-
10 characterized and the criteria for perform-
11 ance of the test or tests are well-estab-
12 lished for the intended use, the clinical cir-
13 cumstances under which the in vitro clin-
14 ical test is used, and the availability of
15 other tests (such as confirmatory or ad-
16 junctive tests).

17 “(B) EXCEPTION.—The term ‘high-risk’
18 does not include an in vitro clinical test de-
19 scribed in subparagraph (A) if—

20 “(i) mitigating measures are estab-
21 lished to prevent, detect, or otherwise miti-
22 gate the risk of inaccurate results as de-
23 scribed in subparagraph (A), or—

24 “(ii) an exemption from the definition
25 of such term applies under section 587A.

1 “(10) INDICATIONS FOR USE.—The term ‘indi-
2 cations for use’ means one or more in vitro clinical
3 tests that have all of the following notification ele-
4 ments in common:

5 “(A) Substance or substances measured by
6 the in vitro clinical test, such as an analyte,
7 protein, or pathogen.

8 “(B) Test method.

9 “(C) Test purpose or purposes, as de-
10 scribed in section 201(ss)(1)(A).

11 “(D) Diseases or conditions for which the
12 in vitro clinical test is intended for use, includ-
13 ing intended patient populations.

14 “(E) Context of use, such as in a clinical
15 laboratory, in a health care facility, prescription
16 home use, over-the-counter use, or direct-to-
17 consumer testing.

18 “(11) INSTRUMENT.—The term ‘instrument’
19 means an in vitro clinical test that is hardware in-
20 tended by the hardware’s developer to be used with
21 one or more in vitro clinical tests to generate a clin-
22 ical test result, including software used to effectuate
23 the hardware’s functionality.

24 “(12) INSTRUMENT FAMILY.—The term ‘instru-
25 ment family’ means more than one instrument for

1 which the developer demonstrates and documents,
2 with respect to all such instruments, that all—

3 “(A) have the same basic architecture, de-
4 sign, and performance characteristics, such as
5 tolerance limits and signal range;

6 “(B) have the same intended use or uses
7 and function;

8 “(C) share the same measurement prin-
9 ciples, detection methods, and reaction condi-
10 tions; and

11 “(D) produce the same or similar analyt-
12 ical results from samples of the same specimen
13 type or types.

14 “(13) LABORATORY OPERATIONS.—The term
15 ‘laboratory operations’—

16 “(A) means the conduct of a laboratory ex-
17 amination or other laboratory procedure on ma-
18 terials derived from the human body, including
19 the conduct of an in vitro clinical test and asso-
20 ciated activities within or under the oversight of
21 a laboratory and not related to the design of an
22 in vitro clinical test; and

23 “(B) includes—

1 “(i) performing pre-analytical and
2 post-analytical processes for an in vitro
3 clinical test;

4 “(ii) conducting standard operating
5 procedures; and

6 “(iii) preparing reagents or other test
7 materials that do not meet the definition of
8 a in vitro clinical test for clinical use under
9 section 201(ss).

10 “(14) LOW-RISK.—The term ‘low-risk’, with re-
11 spect to an in vitro clinical test or category of in
12 vitro clinical tests, means that an undetected inac-
13 curate result from such in vitro clinical test, or such
14 category of in vitro clinical tests, when used as in-
15 tended by the developer—

16 “(A) would cause minimal or no harm, or
17 minimal or no disability, or immediately revers-
18 ible harm, or would lead to only a remote risk
19 of adverse patient impact or adverse public
20 health impact, taking into account the degree to
21 which the technology for the intended use of an
22 in vitro clinical test or category of tests is well-
23 characterized and the criteria for performance
24 of the test or category of tests are well-estab-
25 lished for the intended use, the clinical cir-

1 cumstances under which the in vitro clinical
2 test or category of tests is used, and the avail-
3 ability of other tests (such as confirmatory or
4 adjunctive tests); or

5 “(B) would cause a serious adverse health
6 consequence, harm that is reversible, a delay in
7 necessary treatment that is not life-supporting
8 or life-sustaining, or would lead to a serious
9 risk of adverse patient experience or adverse
10 public health impact, but applied mitigating
11 measures have the capacity to ensure the test
12 meets the standard described in subparagraph
13 (A).

14 “(15) MITIGATING MEASURES.—The term
15 ‘mitigating measures’—

16 “(A) means controls, standards, or require-
17 ments that the Secretary determines, based on
18 available evidence—

19 “(i) are necessary for an in vitro clin-
20 ical test, or a category of in vitro clinical
21 tests, to meet the applicable standard; or

22 “(ii) to mitigate the risk of harm en-
23 suing from an inaccurate result such that
24 a test or category of tests subject to such
25 mitigating measures does not meet the def-

1 initiation of high risk, or such that a test or
2 category of tests subject to such mitigating
3 measures is low risk; and

4 “(B) includes, as appropriate, applicable
5 requirements regarding labeling, conformance
6 to performance standards or guidance, perform-
7 ance testing, submission of clinical data, adver-
8 tising, website posting of information, clinical
9 studies, postmarket surveillance, user com-
10 prehension studies, training, and availability of
11 confirmatory laboratory or clinical findings.

12 “(16) SPECIMEN RECEPTACLE.—The term
13 ‘specimen receptacle’ means an in vitro clinical test
14 specifically intended for the holding, storing, or
15 transporting of specimens derived from the human
16 body or for in vitro examination for purposes de-
17 scribed in clause (i) or (ii) of section 201(ss)(1)(A).

18 “(17) TECHNOLOGY.—The term ‘technology’—

19 “(A) means a developer’s grouping of in
20 vitro clinical tests that do not significantly dif-
21 fer in control mechanisms, energy sources, or
22 operating principals and for which design, de-
23 velopment, and manufacturing, including ana-
24 lytical and clinical validation as applicable, of

1 the tests would be addressed in a similar man-
2 ner or through similar procedures; and

3 “(B) may include clot detection, colorimetric (non-immunoassay), electrochemical
4 (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry
5 (non-immunoassay), immunoassay, mass spectrometry or chromatography (such as HPLC),
6 microbial culture, next generation sequencing (also known as ‘NGS’), nephelometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, single-based technology, spectroscopy, and any other
7 technology, as the Secretary determines appropriate.
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16 “(18) TEST.—The term ‘test’, unless otherwise
17 provided, means an in vitro clinical test.

18 “(19) VALID SCIENTIFIC EVIDENCE.—The term
19 ‘valid scientific evidence’—

20 “(A) means, with respect to an in vitro
21 clinical test, evidence—

22 “(i) that has been generated and evaluated by persons qualified by training or
23 experience to do so, using procedures gen-
24

1 erally accepted by other persons so quali-
2 fied; and

3 “(ii) from which it can be fairly and
4 responsibly concluded by qualified experts
5 whether the applicable standard has been
6 met by the in vitro clinical test for its in-
7 tended use; and

8 “(B) may include evidence described in
9 subparagraph (A) consisting of—

10 “(i) peer-reviewed literature;

11 “(ii) clinical guidelines;

12 “(iii) reports of significant human ex-
13 perience with an in vitro clinical test;

14 “(iv) bench studies;

15 “(v) case studies or histories;

16 “(vi) clinical data;

17 “(vii) consensus standards;

18 “(viii) reference standards;

19 “(ix) data registries;

20 “(x) postmarket data;

21 “(xi) real world data;

22 “(xii) clinical trials; and

23 “(xiii) data collected in countries
24 other than the United States if such data
25 are demonstrated to be adequate for the

1 purpose of making a regulatory determina-
2 tion under the applicable standard in the
3 United States.

4 “(20) WELL-CHARACTERIZED.—The term ‘well-
5 characterized’, with respect to an in vitro clinical
6 test, means well-established and well-recognized by
7 the scientific or clinical community, if adequately
8 evidenced by one or more of the following:

9 “(A) Peer-reviewed literature.

10 “(B) Practice guidelines.

11 “(C) Consensus standards.

12 “(D) Recognized standards of care.

13 “(E) Technology in use for many years.

14 “(F) Scientific publication by multiple
15 sites.

16 “(G) Adoption by the scientific or clinical
17 community.

18 “(H) Real world data.

19 **“SEC. 587A. APPLICABILITY.**

20 “(a) IN GENERAL.—

21 “(1) APPLICABILITY OF THIS SUBCHAPTER.—

22 “(A) IN GENERAL.—An in vitro clinical
23 test shall be subject to the requirements of this
24 subchapter, except as otherwise provided this
25 subchapter.

1 “(B) INTERSTATE COMMERCE.—Any in
2 vitro clinical test that is offered for clinical use
3 in the United States is deemed to be introduced
4 into interstate commerce for purposes of enforcing
5 the requirements of this Act.

6 “(C) NON-APPLICABLE REQUIREMENT.—
7 Subject to any exemption or exclusion in this
8 section, an in vitro clinical test shall not be sub-
9 ject to any provision or requirement of this Act
10 other than this subchapter unless such other
11 provision or requirement—

12 “(i) applies expressly to in vitro clin-
13 ical tests; or

14 “(ii) describes the authority of the
15 Secretary when regulating such in vitro
16 clinical tests or subset of in vitro clinical
17 tests, with respect to—

18 “(I) all articles regulated by the
19 Secretary pursuant to this Act; or

20 “(II) a subset of such articles
21 that includes in vitro clinical tests.

22 “(2) LABORATORIES AND BLOOD AND TISSUE
23 ESTABLISHMENTS.—

24 “(A) RELATION TO LABORATORY CERTIFI-
25 CATION PURSUANT TO SECTION 353 OF THE

1 PHSA.—Nothing in this subchapter shall be
2 construed to modify the authority of the Sec-
3 retary with respect to laboratories or clinical
4 laboratories under section 353 of the Public
5 Health Service Act.

6 “(B) AVOIDING DUPLICATION.—In imple-
7 menting this subchapter, the Secretary shall
8 avoid issuing or enforcing regulations that are
9 duplicative of regulations under section 353.

10 “(C) BLOOD AND TISSUE.—Nothing in
11 this subchapter shall be construed to modify the
12 authority of the Secretary with respect to lab-
13 oratories, establishments, or other facilities to
14 the extent they are engaged in the propagation,
15 manufacture, or preparation, including filling,
16 testing, labeling, packaging, and storage, of
17 blood, blood components, human cells, tissues,
18 or tissue products under this Act or section 351
19 or 361 of the Public Health Service Act.

20 “(3) PRACTICE OF MEDICINE.—

21 “(A) IN GENERAL.—Nothing in this sub-
22 chapter shall be construed to limit or interfere
23 with the authority of a health care practitioner
24 to prescribe or administer any legally marketed
25 in vitro clinical test for any condition or disease

1 within a health care practitioner-patient rela-
2 tionship pursuant to applicable Federal or State
3 law.

4 “(B) RULES OF CONSTRUCTION.—

5 “(i) SALE, DISTRIBUTION, LABEL-
6 ING.—Nothing in this paragraph shall be
7 construed to limit the authority of the Sec-
8 retary to establish or enforce restrictions
9 on the sale, distribution, or labeling of an
10 in vitro clinical test under this Act.

11 “(ii) PROMOTION OF UNAPPROVED
12 USES.—Nothing in this paragraph shall be
13 construed to alter any prohibition on the
14 promotion of unapproved uses of legally
15 marketed in vitro clinical tests.

16 “(4) SPECIAL RULE.—

17 “(A) PREMARKET REVIEW APPLICABLE.—
18 Notwithstanding the exemptions from pre-
19 market review under section 587B set forth in
20 subsections (b), (c), (d), (e), (f), (g), (h), (j),
21 and (k) of such section, an in vitro clinical test
22 (including any article for taking or deriving
23 specimens) shall be subject to the requirements
24 of section 587B if the Secretary determines, in
25 accordance with subparagraph (B), that—

1 “(i)(I) there is insufficient valid sci-
2 entific evidence to support the analytical
3 validity or the clinical validity of such in
4 vitro clinical test; and

5 “(II) such in vitro clinical test is
6 being offered by its developer with materi-
7 ally deceptive or fraudulent analytical or
8 clinical claims;

9 “(ii) it is reasonably possible that
10 such in vitro clinical test will cause serious
11 adverse health consequences; or

12 “(iii) in the case of specimen recep-
13 tacles, there is sufficient valid scientific
14 evidence indicating that a specimen recep-
15 tacle did not perform as intended, will not
16 support the analytical validity of tests with
17 which it is used, or as applicable, is not
18 safe for use.

19 “(B) PROCESS.—

20 “(i) REQUEST FOR INFORMATION.—If
21 the Secretary has valid scientific evidence
22 indicating that the criteria listed in sub-
23 paragraph (A) apply to an in vitro clinical
24 test, the Secretary may request that the
25 developer of the test submit information—

1 “(aa) promptly, and not
2 later than 90 days after the date
3 of receipt of such information,
4 submit an application for pre-
5 market review of the test under
6 section 587B; or

7 “(bb) cease to market the
8 test.

9 “(II) EXTENSION.—The Sec-
10 retary may grant an extension to a
11 developer of the 90-day time period
12 under subclause (I)(aa), as appro-
13 priate.

14 “(v) CONTINUED MARKETING.—Dur-
15 ing the period beginning on the date of a
16 request for information under clause (ii)
17 and ending on the date of the disposition
18 of an application for premarket review of
19 the in vitro clinical test under section
20 587B, the developer of the test may con-
21 tinue to market the test for clinical use,
22 unless the Secretary issues an order to the
23 developer under clause (vi) to immediately
24 cease distribution of the test.

1 “(vi) ORDER TO CEASE DISTRIBUTION.—
2

3 “(I) IN GENERAL.—If the devel-
4 oper of an in vitro clinical test fails to
5 submit an application for premarket
6 review of the test by the deadline ap-
7 plicable under clause (iv), or the Sec-
8 retary finds that the criteria listed in
9 subparagraph (A) apply to an in vitro
10 clinical test and that it is in the best
11 interest of the public health, the Sec-
12 retary may issue an order, within 10
13 calendar days of the applicable dead-
14 line or finding by the Secretary, re-
15 quiring the developer of such in vitro
16 clinical test, and any other appro-
17 priate person (including a distributor
18 or retailer of the in vitro clinical test)
19 to immediately—

20 “(aa) cease distribution of
21 the test pending approval of an
22 application for premarket review
23 of the test under section 587B;
24 and

1 “(bb) notify health profes-
2 sionals and other user facilities of
3 the order to cease distribution
4 and advise health care profes-
5 sionals to cease use of such in
6 vitro clinical test.

7 “(II) HEARING AND REVIEW.—
8 An order under subclause (I) shall
9 provide the person subject to the
10 order with an opportunity for an in-
11 formal hearing, to be held not later
12 than 10 days after the date of the
13 issuance of the order, on the actions
14 required by the order and on whether
15 the order should be amended to re-
16 quire a recall of such in vitro clinical
17 test. If, after providing an opportunity
18 for such a hearing, the Secretary de-
19 termines that inadequate grounds
20 exist to support the actions required
21 by the order, the Secretary shall ter-
22 minate the order within 30 days of
23 the hearing. Upon terminating an
24 order, the Secretary shall provide

1 written notice of such termination to
2 the developer.

3 “(vii) AMENDMENT TO REQUIRE RE-
4 CALL.—If the Secretary determines that
5 an order issued under clause (vi) should be
6 amended to include a recall of the in vitro
7 clinical test with respect to which the order
8 was issued, the Secretary shall amend the
9 order to require a recall. In such amended
10 order, the Secretary shall specify a time-
11 frame in which the in vitro clinical test re-
12 call will occur and shall require periodic re-
13 ports to the Secretary describing the
14 progress of the recall. Upon termination of
15 the recall, the Secretary shall provide writ-
16 ten notice of such termination to the devel-
17 oper.

18 “(viii) EFFECT OF TEST APPROVAL.—
19 Any order issued under this paragraph
20 with respect to an in vitro clinical test
21 shall cease to be in effect if such test is
22 granted approval under section 587B, pro-
23 vided that the in vitro clinical test is devel-
24 oped and offered for clinical use in accord-
25 ance with such approval.

1 “(5) EMERGENCY USE.—

2 “(A) IN GENERAL.—In the case of a deter-
3 mination under section 319(a) of the Public
4 Health Service Act or a declaration under sec-
5 tion 564(b) of this Act, an in vitro clinical test
6 is exempt from the requirements of this sub-
7 chapter and may be lawfully marketed in ac-
8 cordance with subparagraph (B).

9 “(B) CRITERIA.—An in vitro clinical test
10 is exempt from the requirements of this sub-
11 chapter and may be lawfully marketed in ac-
12 cordance with the exemption described in sub-
13 paragraph (A) if—

14 “(i) such test—

15 “(I) is submitted for emergency
16 use authorization under section
17 564(b); or

18 “(II) is developed and used in
19 laboratories for which a certificate is
20 in effect under section 353 of the
21 Public Health Service Act to conduct
22 high-complexity testing and the devel-
23 oper; and

24 “(ii) the developer—

1 “(I) validates such in vitro clin-
2 ical test prior to use;

3 “(II) notifies the Secretary of the
4 assay validation; and

5 “(III) submits an emergency use
6 authorization application under sec-
7 tion 564 within 15 calendar days of
8 marketing the test.

9 “(C) DISPOSITION OF PRODUCT.—With re-
10 spect to a previously unapproved in vitro clin-
11 ical test or an in vitro clinical test with an un-
12 approved use, for which an emergency use au-
13 thorization under section 564(b) ceases to be
14 effective, the Secretary shall consult with the
15 manufacturer of such product with respect to
16 the appropriate disposition of the product.

17 “(D) STREAMLINING OF APPLICATION RE-
18 VIEW.—A developer may include any data or in-
19 formation already submitted to the Secretary
20 within the emergency use authorization as a
21 part of a premarket application under section
22 587B or a technology certification application
23 under section 587D.

24 “(6) EFFECT ON OTHER LAWS.—Any in vitro
25 clinical test that is lawfully marketed under this Act,

1 including tests that are approved under section
2 587B, cleared pursuant to an active technology cer-
3 tification order under section 587D, or exempt from
4 premarket review under an exemption in this sec-
5 tion, shall be eligible for introduction into interstate
6 commerce except as otherwise provided in this sub-
7 chapter.

8 “(b) COMPONENTS AND PARTS.—

9 “(1) EXEMPTION.—

10 “(A) IN GENERAL.—Subject to subpara-
11 graph (B), a component, part, or raw material
12 described in section 201(ss)(1)(B)(v) is exempt
13 from the requirements of this subchapter if it
14 is—

15 “(i) intended for further development
16 as described in paragraph (2); or

17 “(ii) otherwise to be regulated based
18 on its risk when used as intended by the
19 developer, notwithstanding its subsequent
20 use by a developer as a component, part,
21 or raw material of another in vitro clinical
22 test.

23 “(B) INAPPLICABILITY TO OTHER
24 TESTS.—Notwithstanding subparagraph (A), an
25 in vitro clinical test that is described in section

1 201(ss)(1)(B) and that uses a component or
2 part described in such subparagraph shall be
3 subject to the requirements of this subchapter,
4 unless the test is otherwise exempt under this
5 section.

6 “(2) FURTHER DEVELOPMENT.—A component,
7 part, or raw material (as described in paragraph
8 (1)(A)) is intended for further development (for pur-
9 poses of such paragraph) if—

10 “(A) it is intended solely for use in the de-
11 velopment of another in vitro clinical test; and

12 “(B) in the case of such a test that is in-
13 troduced or delivered for introduction into
14 interstate commerce after the date of enactment
15 of the Verifying Accurate Leading-edge IVCT
16 Development Act of 2021, the labeling of such
17 test bears the following statement: ‘This prod-
18 uct is intended solely for further development of
19 an in vitro clinical test and is exempt from
20 FDA regulation. This product must be evalu-
21 ated by the in vitro clinical test developer if it
22 is used with or in the development of an in vitro
23 clinical test.’.

24 “(c) GRANDFATHERED TESTS.—

1 “(2) CRITERIA FOR EXEMPTION.—An in vitro
2 clinical test is exempt as specified in paragraph (1)
3 if the test—

4 “(A)(i) was first offered for clinical use by
5 such laboratory before the date of enactment of
6 the Verifying Accurate Leading-edge IVCT De-
7 velopment Act of 2021;

8 “(ii) was developed by a clinical laboratory
9 for which a certificate was in effect under sec-
10 tion 353 of the Public Health Service Act that
11 meets the requirements under such section 353
12 for performing high-complexity testing; and

13 “(iii) is performed—

14 “(I) in the same clinical laboratory in
15 which it was developed;

16 “(II) by another clinical laboratory for
17 which a certificate is in effect under sec-
18 tion 353 within the same corporate organi-
19 zation and having common ownership by
20 the same parent corporation; or

21 “(III) by a laboratory within a public
22 health laboratory network coordinated or
23 managed by the Centers for Disease Con-
24 trol and Prevention;

1 “(B) does not have in effect an approval
2 under section 515, a clearance under section
3 510(k), an authorization under section
4 513(f)(2), or an exemption under section
5 520(m); and

6 “(C) is not modified on or after the date
7 of enactment of the Verifying Accurate Lead-
8 ing-edge IVCT Development Act of 2021 by its
9 initial developer (or another person) in a man-
10 ner such that the test is a new in vitro clinical
11 test under subsection (l).

12 “(3) MODIFICATIONS.—In the case of a modi-
13 fication to an in vitro clinical test that is exempt as
14 specified in paragraph (1) or such modification is
15 otherwise not subject to premarket review pursuant
16 to section 587A(l), the test continues to qualify for
17 such exemption if the person modifying such test—

18 “(A) documents each such modification
19 and maintains a summary of the basis for such
20 determination; and

21 “(B) provides such documentation and
22 summary to the Secretary upon request or in-
23 spection.

24 “(d) TESTS EXEMPT FROM SECTION 510(k).—

1 “(1) EXEMPTION.—An in vitro clinical test is
2 exempt from premarket review under section 587B
3 and may be lawfully marketed subject to the other
4 applicable requirements of this Act, if the in vitro
5 clinical test—

6 “(A)(i) was offered for clinical use prior to
7 the date of enactment of the Verifying Accurate
8 Leading-edge IVCT Development Act of 2021;
9 and

10 “(ii) immediately prior to such date of en-
11 actment was exempt pursuant to subsection (l)
12 or (m)(2) of section 510 from the requirements
13 for submission of a report under section 510(k);
14 or

15 “(B)(i) was not offered for clinical use
16 prior to such date of enactment;

17 “(ii) is not a test platform; and

18 “(iii) falls within a category of tests that
19 was exempt from the requirements for submis-
20 sion of a report under section 510(k) as of such
21 date of enactment (including class II devices
22 and excluding class I devices described in sec-
23 tion 510(l)).

24 “(2) EFFECT ON SPECIAL CONTROLS.—For any
25 in vitro clinical test, or category of in vitro clinical

1 tests, that is exempt from premarket review based
2 on the criteria in paragraph (2), any special control
3 that applied to a device within a predecessor cat-
4 egory immediately prior to the date of enactment of
5 Verifying Accurate Leading-edge IVCT Development
6 Act of 2021 shall be deemed a mitigating measure
7 applicable under section 587E to an in vitro clinical
8 test within the successor category, except to the ex-
9 tent such mitigating measure is withdrawn or
10 changed in accordance with section 587E.

11 “(3) NEAR-PATIENT TESTING.—Not later than
12 1 year after the date of enactment of the Verifying
13 Accurate Leading-edge IVCT Development Act of
14 2021, the Secretary shall issue draft guidance indi-
15 cating categories of tests that shall be exempt from
16 premarket review under section 587B when offered
17 for near-patient testing (point of care), which were
18 not exempt from submission of a report under sec-
19 tion 510(k) pursuant to subsection (l) or (m)(2) of
20 section 510 and regulations imposing limitations on
21 exemption for in vitro devices intended for near-pa-
22 tient testing (point of care).

23 “(e) LOW-RISK TESTS.—

24 “(1) EXEMPTION.—An in vitro clinical test is
25 exempt from premarket review under section 587B

1 and may be lawfully marketed subject to the other
2 applicable requirements of this Act, including section
3 587I(b)(6), if such test meets the definition of low-
4 risk under section 587.

5 “(2) LIST OF LOW-RISK TESTS.—

6 “(A) IN GENERAL.—The Secretary shall
7 maintain, and make publicly available on the
8 website of the Food and Drug Administration,
9 a list of in vitro clinical tests, and categories of
10 in vitro clinical tests, that are low-risk in vitro
11 clinical tests for purposes of the exemption
12 under this subsection.

13 “(B) INCLUSION.—The list under subpara-
14 graph (A) shall consist of—

15 “(i) all in vitro clinical tests and cat-
16 egories of in vitro clinical tests that are ex-
17 empt from premarket review pursuant to
18 subsection (d)(1) or (d)(3); and

19 “(ii) all in vitro clinical tests and cat-
20 egories of in vitro clinical tests that are
21 designated by the Secretary pursuant to
22 subparagraph (C) as low-risk for purposes
23 of this subsection.

24 “(C) DESIGNATION OF TESTS AND CAT-
25 EGORIES.—Without regard to subchapter II of

1 chapter 5 of title 5, United States Code, the
2 Secretary may designate, in addition to the
3 tests and categories described in subparagraph
4 (B)(i), additional in vitro clinical tests, and cat-
5 egories of in vitro clinical tests, as low-risk in
6 vitro clinical tests for purposes of the exemption
7 under this subsection. The Secretary may make
8 such a designation on the Secretary's own ini-
9 tiative or in response to a request by any per-
10 son. In making such a designation for a test or
11 category of tests, the Secretary shall consider—

12 “(i) whether the test, or category of
13 tests, is low-risk; and

14 “(ii) such other factors as the Sec-
15 retary determines to be relevant to the pro-
16 tection of the public health.

17 “(f) MANUAL TESTS.—

18 “(1) EXEMPTION.—An in vitro clinical test is
19 exempt from all requirements of this subchapter if
20 the output of such in vitro clinical test is the result
21 of direct, manual observation, without the use of
22 automated instrumentation or software for inter-
23 mediate or final interpretation, by a qualified labora-
24 tory professional, and such in vitro clinical test—

1 “(A) is designed, manufactured, and used
2 within a single clinical laboratory for which a
3 certificate is in effect under section 353 of the
4 Public Health Service Act that meets the re-
5 quirements under section 353 for performing
6 high-complexity testing;

7 “(B) is not a high-risk test, or is a high-
8 risk test that the Secretary has determined
9 meets at least one condition in paragraph (2)
10 and is otherwise appropriate for this exemption;
11 and

12 “(C) is not intended for testing donors, do-
13 nations, and recipients of blood, blood compo-
14 nents, human cells, tissues, cellular-based prod-
15 ucts, or tissue-based products.

16 “(2) HIGH-RISK TEST LIMITATION OR CONDI-
17 TION.—A high-risk test may be exempt under para-
18 graph (1) from the requirements of this subchapter
19 only if—

20 “(A) no component or part of such test, in-
21 cluding any reagent, is introduced into inter-
22 state commerce under the exemption under sub-
23 section (b)(1) (relating to components or parts
24 intended for further development), and any ar-
25 ticle for taking or deriving specimens from the

1 human body used in conjunction with the test
2 remains subject to the requirements of this sub-
3 chapter; or

4 “(B) the test has been developed in accord-
5 ance with the applicable test design and quality
6 requirements under section 587J.

7 “(g) HUMANITARIAN TEST EXEMPTION.—

8 “(1) IN GENERAL.—An in vitro clinical test is
9 exempt from premarket review under section 587B
10 and may be lawfully marketed subject to the other
11 applicable requirements of this Act, if—

12 “(A) such in vitro clinical test is intended
13 for use for a disease or condition for which no
14 more than 10,000 (or such other number deter-
15 mined by the Secretary) individuals would be
16 subject to negative or positive diagnosis by such
17 test in the United States per year; and

18 “(B) the developer of the test—

19 “(i) maintains documentation (which
20 may include literature citations in special-
21 ized medical journals, textbooks, special-
22 ized medical society proceedings, govern-
23 mental statistics publications, or, if no
24 such studies or literature citations exist,
25 credible conclusions from appropriate re-

1 search or surveys) demonstrating that such
2 test meets and continues to meet the cri-
3 teria described in this paragraph; and

4 “(ii) makes such documentation avail-
5 able to the Secretary upon request.

6 “(2) CROSS-REFERENCED TESTS.—In order to
7 be eligible for an exemption under this subsection,
8 the developer of a cross-referenced test shall submit
9 a request under section 587H for informal feedback.

10 “(h) CUSTOM TESTS AND LOW-VOLUME TESTS.—An
11 in vitro clinical test is exempt from premarket review
12 under section 587B, the quality requirements under sec-
13 tion 587J, and the notification requirements under section
14 587I, and may be lawfully marketed subject to the other
15 applicable requirements of this Act, if—

16 “(1) such in vitro clinical test—

17 “(A) is a low-volume test performed in a
18 laboratory in which it was developed or devel-
19 oped in a laboratory within the same corporate
20 organization with the laboratory in which such
21 test is performed and is administered to no
22 more than 5 patients per year, unless otherwise
23 determined by the Secretary; or

24 “(B) is a custom test developed or modi-
25 fied to diagnose a unique pathology or physical

1 condition of a specific patient for which no
2 other in vitro clinical test is commercially avail-
3 able in the United States, and is—

4 “(i) not intended for use with respect
5 to other patients; and

6 “(ii) after the development of the cus-
7 tom test, not included in any test menu,
8 template test report, or other promotional
9 materials, and not otherwise advertised;
10 and

11 “(2) the developer of the test—

12 “(A) maintains documentation dem-
13 onstrating that such test meets and continues
14 to meet the applicable criteria described in
15 paragraph (1);

16 “(B) makes such documentation, such as a
17 prescription order requesting the custom test
18 for an individual patient, available to the Sec-
19 retary upon request; and

20 “(C) informs the Secretary, on an annual
21 basis, in a manner prescribed by the Secretary
22 by guidance, that such test was introduced into
23 interstate commerce.

24 “(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

1 “(1) IN GENERAL.—The provisions of this sub-
2 chapter shall not apply to a test intended by the de-
3 veloper to be used solely for public health surveil-
4 lance activities, including the collection and testing
5 of information or biospecimens, conducted, sup-
6 ported, requested, ordered, required, or authorized
7 by a public health authority.

8 “(2) LIMITATION.—The public health surveil-
9 lance activities described in paragraph (1)—

10 “(A) are limited to activities necessary to
11 allow a public health authority to identify, mon-
12 itor, assess, or investigate potential public
13 health signals, onsets of disease outbreaks, or
14 conditions of public health importance (includ-
15 ing trends, risk factors, patterns in diseases,
16 and increases in injuries from using consumer
17 products); and

18 “(B) include activities associated with pro-
19 viding timely situational awareness and priority
20 setting during the course of a threat to the pub-
21 lic health (including natural or man-made dis-
22 asters and deliberate attacks on the United
23 States).

24 “(3) EXCLUSION.—An in vitro clinical test is
25 not excluded from the provisions of this subchapter

1 if such test is intended for use in making clinical de-
2 cisions for individual patients.

3 “(j) LAW ENFORCEMENT OR EMPLOYER TESTING.—

4 An in vitro clinical test that is intended solely for use in
5 forensic analysis, law enforcement activity, or employment
6 purposes is exempt from the requirements of this Act. An
7 in vitro clinical test that is intended for use in making
8 clinical decisions for individual patients, or whose individ-
9 ually identifiable results may be reported back to an indi-
10 vidual patient or the patient’s health care provider, even
11 if also intended for law enforcement or employment testing
12 purposes, is not intended solely for use in law enforcement
13 or employment testing for purposes of this subsection.

14 “(k) IN VITRO CLINICAL TESTS UNDER A TECH-

15 NOLOGY CERTIFICATION ORDER.—An in vitro clinical test
16 that is within the scope of a technology certification order,
17 as described in section 587D(a), is exempt from premarket
18 review under section 587B.

19 “(l) MODIFIED TESTS.—

20 “(1) IN GENERAL.—An in vitro clinical test
21 that is modified, by the initial developer of the test
22 or a different person, is a new in vitro clinical test
23 subject to the requirements of this subchapter if the
24 modification—

1 “(A) affects the analytical or clinical valid-
2 ity of such test;

3 “(B) causes the test to no longer comply
4 with applicable mitigating measures under sec-
5 tion 587E or restrictions under section 587N;
6 or

7 “(C) as applicable, affects the safety of an
8 article for taking or deriving specimens from
9 the human body for a purpose described in sec-
10 tion 201(ss)(1).

11 “(2) EXEMPTIONS.—Notwithstanding para-
12 graph (1), an in vitro clinical test that is modified
13 by the initial developer of the test or a different per-
14 son is not a new in vitro clinical test if the modifica-
15 tion—

16 “(A) is a software update that does not
17 have an adverse effect on the analytical or clin-
18 ical validity or result in an increased risk to pa-
19 tients and consumers;

20 “(B) is made pursuant to methods or cri-
21 teria included in the change protocol premarket
22 submission, amendment, or supplement ap-
23 proved by the Secretary for the in vitro clinical
24 test being modified;

1 “(C) is a labeling change that is appro-
2 priate to address patient or user harm; or

3 “(D) is a specimen-related modification
4 that—

5 “(i) is made to extend specimen sta-
6 bility; or

7 “(ii) aligns with the data and infor-
8 mation submitted in an approved applica-
9 tion for premarket review under section
10 587B or a technology certification order
11 issued under section 587D.

12 “(3) DOCUMENTATION.—When a person modi-
13 fies an in vitro clinical test that was developed by
14 another person, such modified test is exempt from
15 the requirements of this subchapter provided that
16 such person—

17 “(A) documents the modification that was
18 made and the basis for determining that the
19 modification, considering the changes individ-
20 ually and collectively, was not a type of modi-
21 fication described in paragraph (1); and

22 “(B) provides such documentation to the
23 Secretary upon request or inspection.

1 “(m) INVESTIGATIONAL USE.—An in vitro clinical
2 test for investigational use is exempt from the require-
3 ments of this Act, except as provided in section 587R.

4 “(n) TRANSFER OR SALE OF IN VITRO CLINICAL
5 TESTS.—

6 “(1) TRANSFER AND ASSUMPTION OF REGU-
7 LATORY OBLIGATIONS.—If ownership of an in vitro
8 clinical test is sold or transferred in such manner
9 that the developer transfers the regulatory submis-
10 sions and obligations applicable under this sub-
11 chapter with respect to the test, the transferee or
12 purchaser becomes the developer of the test and
13 shall have all regulatory obligations applicable to
14 such a test under this subchapter. The transferee or
15 purchaser shall update the registration and listing
16 information under section 587I for the in vitro clin-
17 ical test.

18 “(2) TRANSFER OR SALE OF PREMARKET AP-
19 PROVAL.—

20 “(A) NOTICE REQUIRED.—If a developer
21 of an in vitro clinical test transfers or sells the
22 approval of the in vitro clinical test, the trans-
23 feror or seller shall—

24 “(i) submit a notice of the transfer or
25 sale to the Secretary and update the reg-

1 istration and listing information under sec-
2 tion 587I for the in vitro clinical test; and

3 “(ii) submit a supplemental applica-
4 tion if required under section 587B(h).

5 “(B) EFFECTIVE DATE OF APPROVAL
6 TRANSFER.—A transfer or sale described in
7 subparagraph (A) shall become effective upon
8 completion of a transfer or sale described in
9 paragraph (1) or the approval of a supple-
10 mental application under section 587B(h) if re-
11 quired, whichever is later. The transferee or
12 purchaser shall update the registration and list-
13 ing information under section 587I for the in
14 vitro clinical test within 15 calendar days of the
15 effective date of the transfer or sale.

16 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-
17 TIFICATION.—

18 “(A) REQUIREMENTS FOR TRANSFER OR
19 SALE OF TECHNOLOGY CERTIFICATION.—An
20 unexpired technology certification can be trans-
21 ferred or sold if the transferee or purchaser—

22 “(i) is an eligible person under section
23 587D(b)(1); and

24 “(ii) maintains, upon such transfer or
25 sale, the site, test design and quality re-

1 requirements, processes and procedures
2 under the scope of technology certification,
3 and scope of the technology certification
4 identified in the applicable technology cer-
5 tification order.

6 “(B) NOTICE REQUIRED.—If a developer
7 of an in vitro clinical test transfers or sells a
8 technology certification order that has not ex-
9 pired, the transferor or seller shall submit a no-
10 tice of the transfer or sale to the Secretary and
11 shall update the registration and listing infor-
12 mation under section 587I for all in vitro clin-
13 ical tests covered by the technology certifi-
14 cation.

15 “(C) EFFECTIVE DATE OF TECHNOLOGY
16 CERTIFICATION TRANSFER.—The transfer of a
17 technology certification shall become effective
18 upon completion of a transfer or sale described
19 in subparagraph (A). The transferee or pur-
20 chaser shall update the registration and listing
21 information under section 587I for the in vitro
22 clinical test within 30 calendar days of the ef-
23 fective date of the technology certification
24 transfer.

1 “(D) NEW TECHNOLOGY CERTIFICATION
2 REQUIRED.—If the requirements of subpara-
3 graph (A)(ii) are not met, the technology cer-
4 tification order may not be transferred and the
5 transferee or purchaser of an in vitro clinical
6 test is required to submit an application for
7 technology certification and obtain a technology
8 certification order prior to offering the test for
9 clinical use.

10 “(o) GENERAL LABORATORY EQUIPMENT.—Any in-
11 strument that does not produce an analytical result, and
12 that functions as a component of pre-analytical procedures
13 related to in vitro clinical tests, is not subject to the re-
14 quirements of this subchapter, provided that—

15 “(1) the instrument is operating in a clinical
16 laboratory that is certified under section 353 of the
17 Public Health Service Act; and

18 “(2) the instrument can be serviced by the
19 manufacturer of such instrument or, if that manu-
20 facturer is no longer in business, a third party with
21 the ability to service such instrument.

22 “(p) INSTRUMENT FAMILIES.—In the case of an in-
23 strument family, premarket approval under section
24 587B(d) of one version of the in vitro clinical test is re-
25 quired, and previous and updated versions of the same test

1 within such instrument family shall be deemed to be sub-
2 ject to the approval pursuant to that section, unless the
3 Secretary determines otherwise, as set forth in guidance.

4 “(q) GENERAL EXEMPTION AUTHORITY.—The Sec-
5 retary may, by order published in the Federal Register
6 following notice and an opportunity for comment, exempt
7 a class of persons from any section under this subchapter
8 upon a finding that such exemption is appropriate for the
9 protection of the public health and other relevant consider-
10 ations.

11 “(r) REGULATIONS.—The Secretary may issue regu-
12 lations to implement this subchapter.

13 **“SEC. 587B. PREMARKET REVIEW.**

14 “(a) IN GENERAL.—No person shall introduce or de-
15 liver for introduction into interstate commerce any in vitro
16 clinical test, unless—

17 “(1) an approval of an application filed pursu-
18 ant to subsection (c) or (d) is effective with respect
19 to test; or

20 “(2) the test is exempt under section 587A
21 from premarket review under this section.

22 “(b) TRANSPARENCY AND PREDICTABILITY.—

23 “(1) PRE-SUBMISSION MEETING OR REQUEST
24 FOR INFORMAL FEEDBACK.—Pursuant to section
25 587H, prior to filing an application under subsection

1 (c) or (d), any person may request a meeting or
2 written correspondence with the Secretary to discuss
3 the eligibility of an in vitro clinical test for pre-
4 market review or other information related to the fil-
5 ing of an application. The Secretary shall respond to
6 such request within 45 calendar days.

7 “(2) STREAMLINING OF APPLICATIONS.—

8 “(A) PREMARKET APPLICATION AND
9 TECHNOLOGY CERTIFICATION.—If a person
10 files a premarket application under this section
11 and provides any additional documentation re-
12 quired under section 587D, the in vitro clinical
13 test that is the subject of the application may
14 be utilized as the representative test reviewed
15 by the Secretary to provide an approval for
16 both a premarket application under this section
17 and a technology certification order under sec-
18 tion 587D.

19 “(B) REPRESENTATIVE ASSAYS FOR PRE-
20 MARKET APPROVAL.—With respect to a tech-
21 nology certification application filed under sec-
22 tion 587D, the representative test, as described
23 in subparagraph (A), used to issue a technology
24 certification order under section 587D shall be

1 deemed a test with premarket approval under
2 this section.

3 “(c) APPLICATION.—

4 “(1) FILING.—Any person may file with the
5 Secretary an application for premarket approval of
6 an in vitro clinical test.

7 “(2) APPLICATION CONTENT.—An application
8 submitted under paragraph (1) with respect to an in
9 vitro clinical test shall include the following, in such
10 format as the Secretary specifies:

11 “(A) General information regarding the in
12 vitro clinical test, including—

13 “(i) the name and address of the ap-
14 plicant;

15 “(ii) the table of contents for the ap-
16 plication and the identification of the infor-
17 mation the applicant claims as trade secret
18 or confidential commercial or financial in-
19 formation;

20 “(iii) a description of the test’s in-
21 tended use;

22 “(iv) an explanation regarding test
23 function and any significant performance
24 characteristics; and

1 “(v) an explanation of how the devel-
2 opment and validation activities support
3 the test meeting the applicable standard.

4 “(B) A summary of the data and informa-
5 tion in the application for the in vitro clinical
6 test, including—

7 “(i) a brief description of any existing
8 alternative practices or procedures for di-
9 agnosing the disease or condition for which
10 the in vitro clinical test is intended, as ap-
11 plicable;

12 “(ii) a brief description of the foreign
13 and domestic marketing history of the test,
14 if any, including a list of all countries in
15 which the test has been marketed and a
16 list of all countries in which the test has
17 been withdrawn from marketing for any
18 reason related to the applicable standard
19 of the in vitro clinical test, if known by the
20 applicant;

21 “(iii) a summary of the any studies
22 submitted for such test, including a de-
23 scription of the objective of the study, a
24 description of the experimental design of
25 the study, a brief description of how the

1 data were collected and analyzed, a brief
2 description of the results of the technical
3 data submitted, and a brief description of
4 any nonclinical or clinical studies;

5 “(iv) a risk assessment of the test;
6 and

7 “(v) conclusions drawn from any stud-
8 ies described in clause (iii), including a dis-
9 cussion demonstrating that the data and
10 information in the application constitute
11 valid scientific evidence and meet the appli-
12 cable standard under section 587(2), an
13 explanation of how the development and
14 validation activities, as applicable, support
15 that the test meets the applicable standard
16 under section 587(2), and a discussion of
17 any adverse effects of the test on health
18 and proposals to mitigate those risks, if
19 any.

20 “(C) The signature of the person filing the
21 premarket application or an authorized rep-
22 resentative.

23 “(D) A bibliography of all published re-
24 ports reasonably known to the applicant related
25 to such test and a discussion of data and infor-

1 mation relevant to the evaluation of the applica-
2 ble standard that may be met by such test.

3 “(E) A statement that the applicant be-
4 lieves to the best of the applicant’s knowledge
5 that all data and information submitted to the
6 Secretary are truthful and accurate and that no
7 material fact has been omitted in the applica-
8 tion.

9 “(F) Except as provided under subsection
10 (d), applicable information regarding the meth-
11 ods used in, or the facilities or controls used
12 for, the development of the test to demonstrate
13 compliance with the applicable quality require-
14 ments under section 587J.

15 “(G) Information demonstrating compli-
16 ance with any relevant—

17 “(i) mitigating measures under sec-
18 tion 587E; and

19 “(ii) standards established or recog-
20 nized under section 514 prior to the date
21 of enactment of the Verifying Accurate
22 Leading-edge IVCT Development Act of
23 2021, or, after applicable standards are es-
24 tablished or recognized under section
25 587Q, with such standards.

1 “(H) Valid scientific evidence to support
2 analytical and clinical validity of the test, which
3 shall include—

4 “(i) summary information for all sup-
5 porting validation studies performed; and

6 “(ii) raw data, such as tabulations of
7 data and results as required under section
8 814.20(b)(6)(ii) of title 21, Code of Fed-
9 eral Regulations (or any successor regula-
10 tions);

11 “(iii) for nonclinical laboratory studies
12 involving the test, a statement that studies
13 were conducted in compliance with applica-
14 ble good laboratory practices; and

15 “(iv) for investigations involving
16 human subjects, statements that any clin-
17 ical investigation involving human subjects
18 was conducted in compliance with applica-
19 ble—

20 “(I) institutional review board
21 regulations;

22 “(II) informed consent regula-
23 tions; and

24 “(III) investigational use require-
25 ments in section 587R.

1 “(I) To the extent the application seeks
2 authorization to make modifications to the test
3 within the scope of the approval, a change pro-
4 tocol that includes validation procedures and
5 acceptance criteria for anticipated modifications
6 that could be made to the test within the scope
7 of the approval.

8 “(J) Proposed labeling, in accordance with
9 the requirements of section 587K.

10 “(K) Such other data or information as
11 the Secretary may require in accordance with
12 the least burdensome requirements of sub-
13 section (j).

14 “(3) GUIDANCE FOR PREMARKET AND SPECIAL
15 PREMARKET APPLICATIONS.—In accordance with
16 section 5 of the Verifying Accurate Leading-edge
17 IVCT Development Act of 2021, the Secretary shall
18 issue draft guidance detailing the information to be
19 provided in a premarket application and special pre-
20 market application under this section. The Secretary
21 shall issue final guidance not later than 90 calendar
22 days after the close of the comment period for such
23 guidance.

24 “(4) REFUSE TO FILE A PREMARKET OR SPE-
25 CIAL PREMARKET APPLICATION.—If, after receipt of

1 an application under this section, the Secretary re-
2 fuses to file such application, the Secretary shall
3 provide to the developer, within 60 calendar days of
4 receipt of such application, a description of the rea-
5 son for such refusal, and identify the information re-
6 quired, if any, to allow for the filing of the applica-
7 tion.

8 “(5) SUBSTANTIVE REVIEW FOR DEFICIENT AP-
9 PPLICATION.—If, after receipt of an application under
10 this section, the Secretary determines that any por-
11 tion of such application is deficient, the Secretary
12 shall provide to the applicant, within 75 calendar
13 days of receipt of such application, a description of
14 such deficiencies and identify the information re-
15 quired to correct such deficiencies.

16 “(d) SPECIAL PREMARKET REVIEW.—

17 “(1) IN GENERAL.—Any person may file with
18 the Secretary an application for special premarket
19 approval for—

20 “(A) an instrument;

21 “(B) a specimen receptacle;

22 “(C) an in vitro clinical test eligible for a
23 technology certification order under section
24 587D; or

1 “(D) a first-of-a-kind test (unless it is a
2 high-risk test), a direct-to-consumer test, or
3 cross-referenced test that does not have miti-
4 gating measures.

5 “(2) APPLICATION CONTENT.—An application
6 under paragraph (1) shall include—

7 “(A) the information required for applica-
8 tions submitted under subsection (c)(2), except
9 that applications under paragraph (1) need not
10 include—

11 “(i) quality requirement information;

12 or

13 “(ii) raw data unless explicitly re-
14 quested by the Secretary;

15 “(B) in the case of a specimen receptacle,
16 safety information; and

17 “(C) data, as applicable, to support soft-
18 ware validation, electromagnetic compatibility,
19 and electrical safety, and information dem-
20 onstrating compliance with maintaining quality
21 systems documentation.

22 “(3) 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 587P need not occur unless requested by the Sec-
2 retary.

3 “(e) INSTRUMENT FAMILY.—When an in vitro clin-
4 ical test has been approved, or is otherwise legally mar-
5 keted, for use on a specific approved or legally marketed
6 instrument within an instrument family, a submission
7 under this section shall not be required for that in vitro
8 clinical test in order for it to be used on a new instrument
9 within that instrument’s family.

10 “(f) AMENDMENTS TO AN APPLICATION.—

11 “(1) IN GENERAL.—An applicant may amend
12 an original or supplemental application under sub-
13 section (c) or (d).

14 “(2) REQUIRED AMENDMENT OR SUPPLE-
15 MENT.—An applicant shall amend or supplement an
16 application submitted under subsection (c) or (d) if
17 the applicant becomes aware of information that—

18 “(A) could reasonably affect an evaluation
19 of whether the applicable standard has been
20 met; or

21 “(B) could reasonably affect the statement
22 of contraindications, warnings, precautions, and
23 adverse reactions in the proposed labeling.

24 “(3) REQUEST FOR AMENDMENT OR SUPPLE-
25 MENT.—The Secretary may request that an appli-

1 cant amend or supplement an application under sub-
2 section (c) or (d) with any information necessary for
3 review under this section.

4 “(g) ACTION ON AN APPLICATION FOR PREMARKET
5 APPROVAL.—

6 “(1) REVIEW.—

7 “(A) DISPOSITION.—As promptly as possible,
8 but not later than 90 calendar days after
9 an application under subsection (c) is accepted
10 for submission (unless the Secretary determines
11 that an extension is necessary to review one or
12 more major amendments to the application), or
13 not later than 60 calendar days after an appli-
14 cation under subsection (d) is accepted for sub-
15 mission, the Secretary, after considering any
16 applicable report and recommendations pursu-
17 ant to advisory committees under section 587G,
18 or prior to the establishment of such advisory
19 committees, any recommendations by a classi-
20 fication panel under section 513, shall issue an
21 order approving the application, unless the Sec-
22 retary finds that the grounds for approval in
23 paragraph (2) are not met.

24 “(B) RELIANCE ON PROPOSED LABEL-
25 ING.—In determining whether to approve or

1 deny an application under paragraph (1), the
2 Secretary shall rely on the intended use in-
3 cluded in the proposed labeling, provided that
4 such labeling is not false or misleading based on
5 a fair evaluation of all material facts.

6 “(2) APPROVAL OF AN APPLICATION.—

7 “(A) IN GENERAL.—The Secretary shall
8 approve an application submitted under sub-
9 section (c) with respect to an in vitro clinical
10 test if the Secretary finds that there is a rea-
11 sonable assurance that the applicable standard
12 is met, and—

13 “(i) except as provided under sub-
14 section (d), the applicant is in compliance
15 with applicable quality requirements in sec-
16 tion 587J or as otherwise specified in a
17 condition of approval, or maintains the
18 documentation required to be in compli-
19 ance with such requirements if the appli-
20 cant is not required to submit such docu-
21 mentation as a part of the application
22 under this section;

23 “(ii) the application does not contain
24 a false statement of material fact;

1 “(iii) based on a fair evaluation of all
2 material facts, the proposed labeling is
3 truthful and non-misleading and complies
4 with the requirements of section 587K;

5 “(iv) except as provided under sub-
6 section (d), the applicant permits, if re-
7 quested, authorized employees of the Food
8 and Drug Administration and persons ac-
9 credited under section 587P an oppor-
10 tunity—

11 “(I) to inspect at a reasonable
12 time and in a reasonable manner the
13 facilities and all pertinent equipment,
14 finished and unfinished materials,
15 containers, and labeling therein, in-
16 cluding all things (including records,
17 files, papers, and controls) bearing on
18 whether an in vitro clinical test is
19 adulterated, misbranded, or otherwise
20 in violation of this Act; and

21 “(II) to view and to copy and
22 verify all records pertinent to the ap-
23 plication and the in vitro clinical test;

24 “(v) the test conforms with any appli-
25 cable performance standards under section

1 587Q and any applicable mitigating meas-
2 ures under section 587E; and

3 “(vi) all nonclinical laboratory studies
4 and clinical investigations involving human
5 subjects that are described in the applica-
6 tion were conducted in a manner that
7 meets the requirements of this section.

8 “(B) CONDITIONS OF APPROVAL.—An
9 order approving an application pursuant to this
10 paragraph may require conditions of approval
11 for the in vitro clinical test, including conform-
12 ance with performance standards under section
13 587Q and restrictions under section 587N.

14 “(C) FIRST-OF-A-KIND TEST.—For a first-
15 of-a-kind in vitro clinical test, an order approv-
16 ing an application pursuant to this paragraph—

17 “(i) may impose requirements for
18 tests with the same indications for use, in-
19 cluding conformance with performance
20 standards under section 587Q and miti-
21 gating measures under section 587E, and
22 comply with restrictions under section
23 587N; and

24 “(ii) shall indicate whether subsequent
25 in vitro clinical tests with the same in-

1 tended use may meet an exemption set
2 forth in section 587A.

3 “(D) PUBLICATION.—The Secretary shall
4 publish each order approving an application
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 grant the approval, except to the
9 extent the Secretary determines that such
10 order—

11 “(i) contains commercially confidential
12 or trade secret information; or

13 “(ii) relates to national security or
14 countermeasures is restricted from disclo-
15 sure pursuant to statutory provisions other
16 than this section.

17 “(3) REVIEW OF DENIALS.—An applicant
18 whose application submitted under subsection (c) or
19 (d) has been denied approval may, by petition filed
20 not more than 60 calendar days after the date on
21 which the applicant receives notice of such denial,
22 obtain review of the denial in accordance with sec-
23 tion 587O.

24 “(h) SUPPLEMENTS TO AN APPLICATION.—

1 “(1) RISK ANALYSIS.—Prior to implementing
2 any modification to an in vitro clinical test, the hold-
3 er of the application approved under subsection (c)
4 or (d) for such test shall perform risk analyses in
5 accordance with section 587J, unless such modifica-
6 tion is included in the change protocol submitted by
7 the applicant and approved under this section or ex-
8 empt under section 587A(l).

9 “(2) SUPPLEMENT REQUIREMENT.—

10 “(A) IN GENERAL.—Except as provided in
11 subparagraph (B), or otherwise specified by the
12 Secretary, the holder of the application ap-
13 proved under subsection (g) for an in vitro clin-
14 ical test shall submit to the Secretary and re-
15 ceive approval of a supplement before imple-
16 menting a modification to the test, unless such
17 modification is exempt under section 587A(l).

18 “(B) ADJUSTMENTS TO CHANGE PRO-
19 TOCOL.—A person may submit under this para-
20 graph a supplemental application adjusting the
21 change protocol of the test at any time after the
22 initial filing of an application under subsection
23 (c) or (d).

24 “(C) EXCEPTIONS.—Subject to subpara-
25 graphs (D) and (E), and so long as the holder

1 of an approved application submitted under
2 subsection (c) or (d) for an in vitro clinical test
3 does not add a manufacturing site, or change
4 activities at an existing manufacturing site,
5 with respect to the test, the holder may, with-
6 out prior approval of a supplement, implement
7 the following modifications to the test:

8 “(i) Modifications included in and im-
9 plemented in accordance with an approved
10 change protocol under subsection (c)(2)(I).

11 “(ii) Modifications that do not
12 change—

13 “(I) the analytical or clinical va-
14 lidity of the test;

15 “(II) the intended use of the test
16 unless provided under an approved
17 change protocol under subsection
18 (c)(2)(I); or

19 “(III) the safety of the specimen
20 receptacles.

21 “(iii) Labeling changes to appro-
22 priately address a safety concern.

23 “(iv) Modifications that are exempt
24 under section 587A(l).

1 “(D) REPORTING FOR CHANGE PROTOCOL
2 MODIFICATIONS.—As a component of the report
3 required under subsection (k), the holder of an
4 application approved under subsection (g) for
5 an in vitro clinical test shall—

6 “(i) report any modification to the
7 test described in clause (i) or (ii) of sub-
8 paragraph (C) in the next annual report
9 for the test under subsection (k) following
10 the date on which the test, with such modi-
11 fication, is introduced into interstate com-
12 merce; and

13 “(ii) include in such report—

14 “(I) a description of the modi-
15 fication; and

16 “(II) as applicable, a summary of
17 the analytical validity and clinical va-
18 lidity of the test, as modified, and any
19 changes to acceptance criteria.

20 “(E) REPORTING FOR OTHER CATEGORY
21 OF EXCEPTIONS.—The holder of the application
22 approved under subsection (e) or (d) for an in
23 vitro clinical test shall—

24 “(i) report to the Secretary any modi-
25 fication to the test described in clause (iii)

1 of subparagraph (C) not more than 60
2 days after the date on which the test, with
3 the modification, is introduced into inter-
4 state commerce; and

5 “(ii) include in the report—

6 “(I) a summary of the relevant
7 change or changes;

8 “(II) the rationale for imple-
9 menting such change or changes; and

10 “(III) a description of how the
11 change or changes were evaluated.

12 “(F) REQUEST FOR SUPPLEMENT.—Upon
13 review of the information received under sub-
14 paragraph (D) and a finding that the relevant
15 modification is inconsistent with the standard
16 specified under subparagraph (C), the Secretary
17 may require a supplement under subparagraph
18 (A). If the Secretary determines that a supple-
19 ment under subparagraph (A) is required, the
20 Secretary shall notify the applicant of such de-
21 termination. Such notification shall include a
22 justification for the submission of a supplement.
23 Prior to the submission of a supplement under
24 this subparagraph, the applicant may request a
25 meeting or written correspondence to gain agen-

1 cy feedback as to the necessity of such supple-
2 mental filing. The Secretary shall respond to
3 such meeting request within 30 calendar days
4 of receipt.

5 “(3) CONTENTS OF SUPPLEMENT.—Unless oth-
6 erwise specified by the Secretary, a supplement
7 under this subsection shall include—

8 “(A) for modifications other than manufac-
9 turing site changes—

10 “(i) a description of the modification;

11 “(ii) data to demonstrate that the ap-
12 plicable standard is met;

13 “(iii) acceptance criteria; and

14 “(iv) any revised labeling; and

15 “(B) for manufacturing site changes—

16 “(i) the information listed in subpara-
17 graph (A); and

18 “(ii) information regarding the meth-
19 ods used in, or the facilities or controls
20 used for, the development of the test to
21 demonstrate compliance with the applicable
22 quality requirements under section 587J.

23 “(4) ADDITIONAL DATA.—The Secretary may
24 require, when necessary, data to evaluate a modifica-
25 tion to an in vitro clinical test that is in addition to

1 the data otherwise required under the preceding
2 paragraphs if the data request is in accordance with
3 the least burdensome requirements under subsection
4 (j).

5 “(5) CONDITIONS OF APPROVAL.—In an order
6 approving a supplement under this subsection, the
7 Secretary may require conditions of approval for the
8 in vitro clinical test, including compliance with re-
9 strictions under section 587N and conformance to
10 performance standards under section 587Q.

11 “(6) APPROVAL.—The Secretary shall approve
12 a supplement under this subsection if—

13 “(A) the data demonstrate that the modi-
14 fied in vitro clinical test meets the applicable
15 standard; and

16 “(B) the holder of the application approved
17 under subsection (g) for the test has dem-
18 onstrated compliance with applicable quality
19 and inspection requirements, as applicable and
20 appropriate.

21 “(7) PUBLICATION.—The Secretary shall pub-
22 lish on the public website of the Food and Drug Ad-
23 ministration notice of any order approving a supple-
24 ment under this subsection, except that such publi-
25 cation shall exclude—

1 “(ii) there is a reasonable likelihood
2 that the test would cause death or serious
3 adverse health consequences, including by
4 causing the absence, delay, or discontinu-
5 ation of life-saving or life sustaining med-
6 ical treatment.

7 “(B) CONTENT.—An order under subpara-
8 graph (A) withdrawing approval of an applica-
9 tion shall state each ground for withdrawal and
10 shall notify the holder of such application 60
11 calendar days prior to issuing such order.

12 “(C) PUBLICATION.—The Secretary shall
13 publish any order under subparagraph (A) on
14 the public website of the Food and Drug Ad-
15 ministration, except that such publication shall
16 exclude—

17 “(i) commercial confidential or trade
18 secret information; and

19 “(ii) any other information that the
20 Secretary determines to relate to national
21 security or countermeasures or to be re-
22 stricted from disclosure pursuant to an-
23 other provision of law.

24 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
25 after providing due notice and an opportunity for an

1 informal hearing to the holder of an approved appli-
2 cation for an in vitro clinical test under this section,
3 the Secretary determines there is a reasonable likeli-
4 hood that the in vitro clinical test would cause death
5 or serious adverse health consequences, including by
6 causing the absence, delay, or discontinuation of life-
7 saving or life-sustaining medical treatment, the Sec-
8 retary shall by order temporarily suspend the ap-
9 proval of the application. If the Secretary issues
10 such an order, the Secretary shall proceed expedi-
11 tiously under paragraph (1) to withdraw approval of
12 such application.

13 “(j) 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 provide a reasonable
17 assurance of analytical and clinical validity, or appli-
18 cable standard, and other regulatory requirements,
19 as determined by the Secretary.

20 “(2) NECESSARY DEFINED.—For purposes of
21 paragraph (1) and paragraph (3), the term ‘nec-
22 essary’ means the minimum required information
23 that would support a determination by the Secretary
24 that the application provides a reasonable assurance
25 of analytical and clinical validity, or other applicable

1 standard or regulatory requirement, as determined
2 by the Secretary.

3 “(3) CONSIDERATION OF ROLE OF
4 POSTMARKET INFORMATION.—For purposes of this
5 subsection, the Secretary shall consider the role of
6 postmarket information in determining the least bur-
7 densome appropriate means necessary to dem-
8 onstrate that the applicable standard and other reg-
9 ulatory requirements have been met.

10 “(k) ANNUAL REPORT.—

11 “(1) IN GENERAL.—Unless the Secretary speci-
12 fies otherwise, the holder of an approved application
13 under this section shall submit an annual report
14 each year at a time designated by the Secretary in
15 the approval order. Such report shall—

16 “(A) identify all modifications required to
17 be reported that an approved application holder
18 has made to any test that is covered by the ap-
19 proval order, including any modification that
20 requires a supplement under subsection (h)(2);
21 and

22 “(B) include any other information re-
23 quired by the Secretary.

24 “(2) EXCEPTION.—The annual reporting re-
25 quirement in paragraph (1) shall not apply to in

1 vitro clinical tests that are deemed to have a pre-
2 market approval based on a prior approval under
3 section 515(c), clearance under section 510(k), or
4 authorization under section 513(f) of this Act, or
5 that are grandfathered under 587A(c).

6 “(l) SERVICE OF ORDERS.—Orders of the Secretary
7 under this section with respect to applications under sub-
8 section (c) or (d) or supplements under subsection (h)
9 shall be served—

10 “(1) in person by any officer or employee of the
11 Department of Health and Human Services des-
12 ignated by the Secretary; or

13 “(2) by mailing the order by registered mail or
14 certified mail or electronic equivalent addressed to
15 the applicant at the last known address in the
16 records of the Secretary.

17 **“SEC. 587C. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

18 “(a) IN GENERAL.—The purpose of this section is
19 to encourage the Secretary to apply efficient and flexible
20 approaches to expedite the development of, and prioritize
21 the review of, in vitro clinical tests that represent break-
22 through technologies, and to provide the Secretary with
23 sufficient authority to do so.

24 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
25 shall establish a program to expedite the development of,

1 and provide for the priority review of, in vitro clinical
2 tests.

3 “(c) ELIGIBILITY.—The program developed under
4 subsection (b) shall be available for any in vitro clinical
5 test that—

6 “(1) provides or enables more effective treat-
7 ment or diagnosis of life-threatening or irreversibly
8 debilitating human disease or conditions compared
9 to existing approved or precertified alternatives; and

10 “(2) is a test—

11 “(A) that represents a breakthrough tech-
12 nology;

13 “(B) for which no approved or precertified
14 alternative exists;

15 “(C) that offers a clinically meaningful ad-
16 vantage over existing approved or precertified
17 alternatives, including the potential, compared
18 to existing approved or precertified alternatives,
19 to reduce or eliminate the need for hospitaliza-
20 tion, improve patient quality of life, facilitate
21 patients’ ability to manage their own care (such
22 as through self-directed personal assistance), or
23 establish long-term clinical efficiencies; or

24 “(D) the availability of which is in the best
25 interest of patients or public health.

1 “(d) DESIGNATION.—

2 “(1) REQUEST.—To receive breakthrough ap-
3 proval under this section, an applicant may request
4 that the Secretary designate the in vitro clinical test
5 for expedited development and priority review. Any
6 such request for designation may be made at any
7 time prior to the submission of an application under
8 section 587B, and shall include information dem-
9 onstrating that the test is eligible for designation
10 under subsection (c).

11 “(2) DETERMINATION.—Not later than 60 cal-
12 endar days after the receipt of a request under para-
13 graph (1), the Secretary shall determine whether the
14 in vitro clinical test that is the subject of the request
15 meets the criteria described in subsection (c). If the
16 Secretary determines that the test meets the criteria,
17 the Secretary shall designate the test for expedited
18 development and priority review.

19 “(3) REVIEW.—Review of a request under para-
20 graph (1) shall be undertaken by a team that is
21 composed of experienced staff and senior managers
22 of the Food and Drug Administration.

23 “(4) WITHDRAWAL.—

24 “(A) IN GENERAL.—The designation of an
25 in vitro clinical test under this subsection is

1 deemed to be withdrawn, and such in vitro clin-
2 ical test shall no longer be eligible for designa-
3 tion under this section, if an application for ap-
4 proval under section 587B is denied. Such test
5 shall be eligible for designation upon a new re-
6 quest for such designation.

7 “(B) EXCEPTION.—The Secretary may not
8 withdraw a designation granted under this sub-
9 section based on the subsequent approval or
10 technology certification of another test that—

11 “(i) is designated under this section;

12 or

13 “(ii) was given priority review under
14 section 515B.

15 “(e) ACTIONS.—For purposes of expediting the devel-
16 opment and review of in vitro clinical tests under this sec-
17 tion, the Secretary may take the actions and additional
18 actions set forth in paragraphs (1) and (2), respectively,
19 of section 515B(e) when reviewing such tests. Any ref-
20 erence or authorization in section 515B(e) with respect
21 to a device shall be deemed a reference or authorization
22 with respect to an in vitro clinical test for purposes of this
23 section.

24 “(f) GUIDANCE.—

1 “(1) IN GENERAL.—Not later than one year
2 after the date of enactment of the Verifying Accu-
3 rate Leading-edge IVCT Development Act of 2021,
4 the Secretary shall issue draft guidance on the im-
5 plementation of this section. Such guidance shall—

6 “(A) set forth the process by which a per-
7 son may seek a designation under subsection
8 (d);

9 “(B) provide a template for request under
10 subsection (d);

11 “(C) identify the criteria the Secretary will
12 use in evaluating a request for designation; and

13 “(D) identify the criteria and processes the
14 Secretary will use to assign a team of staff, in-
15 cluding team leaders, to review in vitro clinical
16 tests designated for expedited development and
17 priority review, including any training required
18 for such personnel to ensure effective and effi-
19 cient review.

20 “(2) PROCESS.—Prior to finalizing the guid-
21 ance under paragraph (1), the Secretary shall seek
22 public comment on the draft guidance. The Sec-
23 retary shall issue final guidance one year after the
24 close of the comment period for the draft guidance.

1 “(g) ANNUAL REPORT.—Unless otherwise specified
2 by the Secretary, the requirements under section 587B(k)
3 apply to in vitro clinical tests designated under this sec-
4 tion.

5 “(h) SERVICE OF ORDERS.—Orders of the Secretary
6 under this section shall be served—

7 “(1) in person by any officer or employee of the
8 Department of Health and Human Services des-
9 ignated by the Secretary; or

10 “(2) by mailing the order by registered mail or
11 certified mail or electronic equivalent addressed to
12 the applicant at his last known address in the
13 records of the Secretary.

14 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

15 “(a) IN GENERAL.—

16 “(1) ELIGIBILITY.—Any eligible person may
17 seek a technology certification order in accordance
18 with this section.

19 “(2) EXCEPTION.—An in vitro clinical test is
20 exempt from premarket review under section 587B
21 and may be introduced into interstate commerce if
22 the developer is eligible under this section and the
23 in vitro clinical test—

24 “(A) is an eligible in vitro clinical test
25 under subsection (b)(2); and

1 “(B) falls within the scope of a technology
2 certification order issued under this section that
3 is in effect.

4 “(b) ELIGIBILITY.—

5 “(1) ELIGIBLE PERSON.—In this section, the
6 term ‘eligible person’ means an in vitro clinical test
7 developer unless, at the time such person seeks or
8 would seek technology certification order, the per-
9 son—

10 “(A) has been found to have committed a
11 significant violation of section 353 of the Public
12 Health Service Act, unless—

13 “(i) such violation occurred more than
14 5 years prior to the date on which such
15 technology certification order is or would
16 be sought; or

17 “(ii) such violation has been resolved;
18 or

19 “(B) fails to maintain required certifi-
20 cations under section 353 of the Public Health
21 Service Act, as applicable; or

22 “(C) has been found to have submitted in-
23 formation to the Secretary that—

24 “(i) makes false or misleading state-
25 ments about a technology certification

1 order previously issued or an application
2 approved under section 587B; or

3 “(ii) violates any requirement of this
4 subchapter, where such violation exposes
5 individuals to serious risk of illness, injury,
6 or death.

7 “(2) TECHNOLOGY CERTIFICATION ELIGIBILITY
8 LIMITATIONS.—An in vitro clinical test is not eligible
9 under subsection (a)(2) for exemption from pre-
10 market review under section 587B, if—

11 “(A) such test is—

12 “(i) a component or part of an in
13 vitro clinical test as described in section
14 201(ss)(1)(B)(v);

15 “(ii) an instrument under section
16 201(ss)(1)(B)(ii);

17 “(iii) a specimen receptacle under sec-
18 tion 201(ss)(1)(B)(iii);

19 “(iv) an in vitro clinical test, including
20 reagents used in such tests, intended for
21 use for testing donors, donations, and re-
22 cipients of blood, blood components,
23 human cells, tissues, cellular-based prod-
24 ucts, or tissue-based products; or

1 “(v) a high-risk in vitro clinical test
2 without mitigating measures under section
3 587E, which may include first-of-a-kind in
4 vitro clinical tests, home use in vitro clin-
5 ical tests, cross-referenced in vitro clinical
6 tests, and direct-to-consumer in vitro clin-
7 ical tests.

8 “(c) PUBLIC MEETING AND INPUT.—

9 “(1) PUBLIC DOCKET.—Not later than 30 days
10 after the date of enactment of the Verifying Accu-
11 rate Leading-edge IVCT Development Act of 2021,
12 the Secretary shall establish a public docket to re-
13 ceive comments concerning recommendations for im-
14 plementation of this section, including criteria and
15 procedures for subsections (e) through (j). The pub-
16 lic docket shall remain open for the duration of time
17 that this section remains in effect.

18 “(2) PUBLIC MEETING.—Not later than 180
19 days after the date of enactment of the Verifying
20 Accurate Leading-edge IVCT Development Act of
21 2021, the Secretary shall convene a public meeting
22 to which stakeholders from organizations rep-
23 resenting patients and consumers, academia, and the
24 in vitro clinical test industry are invited in order to
25 discuss the technology certification process including

1 application requirements, inspections, alignment
2 with third-party accreditors, and the definition of
3 ‘technology’ under section 587(17).

4 “(d) REGULATIONS.—The Secretary shall issue regu-
5 lations on technology certification including describing cri-
6 teria or procedures relating to technology certification
7 under this section, which shall be subject to public com-
8 ment for a minimum of 60 days from issuance prior to
9 finalizing such regulations after considering the comments
10 received. The regulation shall include an outline of the ap-
11 plication and recertification process, opportunities to meet
12 with officials of the Food and Drug Administration and
13 plans to streamline inspections.

14 “(e) APPLICATION FOR TECHNOLOGY CERTIFI-
15 CATION.—

16 “(1) IN GENERAL.—A person seeking a tech-
17 nology certification order shall submit an application
18 under this subsection, which shall contain the infor-
19 mation specified under paragraph (2).

20 “(2) CONTENT OF APPLICATION.—An applica-
21 tion for technology certification shall contain—

22 “(A) a statement identifying the scope of
23 the proposed technology certification, which
24 shall be no broader than a single technology in-
25 tended to be offered under the application;

1 “(B) information describing that the per-
2 son seeking a technology certification order is
3 an eligible person under subsection (b)(1);

4 “(C) information describing that the meth-
5 ods used in, and the facilities and controls used
6 for, the development of eligible in vitro clinical
7 tests covered by the scope of the technology cer-
8 tification conform to the applicable quality re-
9 quirements of section 587J;

10 “(D) procedures for analytical validation,
11 including all procedures for validation,
12 verification, and acceptance criteria, and an ex-
13 planation as to how such procedures, when
14 used, provide a reasonable assurance of analyt-
15 ical validity of eligible in vitro clinical tests
16 within the proposed scope of the technology cer-
17 tification order;

18 “(E) procedures for clinical validation, in-
19 cluding all procedures for validation,
20 verification, and acceptance criteria, and an ex-
21 planation as to how such procedures, when
22 used, provide a reasonable assurance of clinical
23 validity of eligible in vitro clinical tests within
24 the proposed scope of the technology certifi-
25 cation order;

1 onstrates the range of procedures that the
2 developer includes in the application under
3 subparagraphs (C), (D), (E), and (F); and

4 “(iv) a brief explanation of the ways
5 in which the procedures included in the ap-
6 plication under subparagraphs (C), (D),
7 (E), and (F) have been applied to the rep-
8 resentative in vitro clinical test or tests;

9 “(H) such other information as the Sec-
10 retary may determine necessary; and

11 “(I) a statement that the applicant believes
12 to the best of the applicant’s knowledge that all
13 data and information submitted to the Sec-
14 retary are truthful and accurate and that no
15 material fact has been omitted.

16 “(3) REFERENCE TO APPROVED PREMARKET
17 APPLICATION UNDER SECTION 587B.—With respect
18 to the content requirements in the technology certifi-
19 cation application described in paragraph (2), a de-
20 veloper may incorporate by reference any content of
21 an application previously submitted by the developer
22 and approved under section 587B.

23 “(f) ACTION ON AN APPLICATION FOR TECHNOLOGY
24 CERTIFICATION.—

25 “(1) SECRETARY RESPONSE.—

1 “(A) IN GENERAL.—As promptly as prac-
2 ticable, and no later than 90 days after receipt
3 of an application under subsection (c), the Sec-
4 retary shall—

5 “(i) issue a technology certification
6 order granting the application, which shall
7 specify the scope of the technology certifi-
8 cation, if the Secretary finds that all of the
9 grounds in paragraph (3) are met; or

10 “(ii) deny the application if the Sec-
11 retary finds (and sets forth the basis of
12 such finding as part of or accompanying
13 such denial) that one or more grounds for
14 granting the application specified in para-
15 graph (3) are not met.

16 “(B) EXTENSION.—The timeline described
17 in subparagraph (A) may be extended by mu-
18 tual agreement between the Secretary and the
19 applicant.

20 “(2) DEFICIENT APPLICATIONS.—

21 “(A) If, after receipt of an application
22 under this section, the Secretary determines
23 that any portion of such application is deficient,
24 the Secretary, not later than 60 days after re-
25 ceipt of such application, shall provide to the

1 applicant a description of such deficiencies and
2 identify the information required to correct
3 such deficiencies.

4 “(B) When responding to the deficiency
5 letter, the applicant may convert the application
6 for technology certification under subsection (c)
7 into a premarket application under section
8 587B.

9 “(3) TECHNOLOGY CERTIFICATION ORDER.—
10 The Secretary shall grant a technology certification
11 order under this section if, on the basis of the infor-
12 mation submitted to the Secretary as part of the ap-
13 plication and any other information with respect to
14 such applicant, the Secretary finds that—

15 “(A) in accordance with subsection
16 (e)(2)(D), there is a showing of reasonable as-
17 surance of analytical validity for all eligible in
18 vitro clinical tests within the proposed scope of
19 the technology certification, as evidenced by the
20 procedures for analytical validation;

21 “(B) in accordance with subsection
22 (e)(2)(E), there is a showing of reasonable as-
23 surance of clinical validity for eligible in vitro
24 clinical tests within the proposed scope of the
25 technology certification, as evidenced by the

1 clinical program, including procedures for clin-
2 ical validation;

3 “(C) the methods used in, or the facilities
4 or controls used for, the development of eligible
5 in vitro clinical tests covered by the proposed
6 scope of the technology certification conform to
7 the applicable requirements of section 587J;

8 “(D) based on a fair evaluation of all ma-
9 terial facts, the applicant’s proposed labeling
10 and advertising is not false or misleading in any
11 particular;

12 “(E) the application does not contain a
13 false statement of material fact;

14 “(F) 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; and

22 “(G) the applicant permits authorized em-
23 ployees of the Food and Drug Administration
24 or persons accredited under this Act an oppor-
25 tunity to inspect at a reasonable time and in a

1 reasonable manner the facilities and all perti-
2 nent equipment, finished and unfinished mate-
3 rials, containers, and labeling therein, including
4 all things (including records, files, papers, and
5 controls) bearing on whether an in vitro clinical
6 test is adulterated, misbranded, or otherwise in
7 violation of this Act, and permits such author-
8 ized employees or persons accredited under this
9 Act to view and to copy and verify all records
10 pertinent to the application and the in vitro
11 clinical test.

12 “(4) EFFECT OF TECHNOLOGY CERTIFICATION
13 ORDER.—An in vitro clinical test or tests within the
14 scope of a granted technology certification order are
15 cleared to be introduced into interstate commerce.

16 “(5) REVIEW OF DENIALS.—If the Secretary
17 denies an application for technology certification, in-
18 cluding an application for renewal under subsection
19 (g), the Secretary will provide a summary of defi-
20 ciencies on which the Secretary based its denial. An
21 applicant whose application has been denied may, by
22 petition filed on or before the date that is 30 cal-
23 endar days after the date upon which such applicant
24 receives notice of such denial, obtain review thereof
25 in accordance with section 5870.

1 “(g) DURATION; SUBSEQUENT SUBMISSIONS.—

2 “(1) ORDER DURATION.—A technology certifi-
3 cation order shall remain in effect until the earlier
4 of—

5 “(A) the expiration of such technology cer-
6 tification order under paragraph (2); or

7 “(B) the withdrawal of such technology
8 certification order under subsection (j).

9 “(2) EXPIRATION.—

10 “(A) An initial technology certification
11 order issued under subsection (f)(3) shall expire
12 4 years after the date that such order is issued,
13 except that if an application for renewal under
14 paragraph (3) has been received not later than
15 30 days prior to the expiration of such order
16 under this paragraph, such order shall expire
17 on the date on which the Secretary has granted
18 or denied the application for renewal. Any such
19 subsequent renewal of a technology certification
20 shall expire on such date specified by the Sec-
21 retary that is not later than 4 years after the
22 date that such technology certification order is
23 issued.

24 “(B) In the event of expiration of tech-
25 nology certification order, the clearance of tests

1 introduced into interstate commerce under such
2 order prior to its expiration pursuant to sub-
3 section (f)(3) remain in effect.

4 “(3) RENEWAL.—

5 “(A) IN GENERAL.—Any person previously
6 granted a technology certification order in ef-
7 fect may seek renewal of such order provided
8 that—

9 “(i) such person is an eligible person
10 under subsection (b)(1);

11 “(ii) the previously granted technology
12 certification order—

13 “(I) is not on temporary hold
14 under subsection (i); and

15 “(II) was not withdrawn under
16 subsection (j); and

17 “(iii) none of the information specified
18 in subsection (e)(2) has substantially
19 changed, except as described in supple-
20 ments to orders granted under paragraph
21 (4).

22 “(B) CONTENT.—An application for re-
23 newal under this paragraph shall include infor-
24 mation concerning one or more representative
25 in vitro clinical tests in accordance with sub-

1 section (e)(2)(G), except that such representa-
2 tive test or tests shall be different from the rep-
3 resentative test or tests relied upon as the rep-
4 resentative assay in any prior technology certifi-
5 cation, if applicable.

6 “(C) PROCESS.—The Secretary’s action on
7 an application for renewal of technology certifi-
8 cation under this paragraph shall be conducted,
9 to the extent practicable, in coordination with
10 inspections conducted under section 353 of the
11 Public Health Service Act, if applicable, and
12 any order resulting from such renewal applica-
13 tion shall be treated as a technology certifi-
14 cation order for purposes of this subchapter.

15 “(4) SUPPLEMENTS AND REPORTS.—

16 “(A) SUPPLEMENTS.—Except as provided
17 in subparagraph (B), any person with a tech-
18 nology certification order in effect may seek a
19 supplement to such order upon a change or
20 changes to the information provided in the ap-
21 plication for technology certification under sub-
22 paragraphs (C), (D), and (E) of subsection
23 (e)(2), provided that—

24 “(i) such person is an eligible person
25 under subsection (b)(1); and

1 “(ii) such change does not expand the
2 scope of the technology certification, unless
3 the Secretary determines that such expan-
4 sion is appropriate.

5 A supplement to an order may contain only in-
6 formation relevant to the change or changes.
7 The Secretary’s action on a supplement shall be
8 in accordance with subsection (f), and any
9 order resulting from such supplement shall be
10 treated as an amendment to a technology cer-
11 tification order that is in effect.

12 “(B) REPORTS.—

13 “(i) IN GENERAL.—If a change is
14 made to an in vitro clinical test or tests
15 that is beyond the scope of a technology
16 certification order but is made in order to
17 address a potential risk to public health by
18 adding a new specification or test method,
19 the person may immediately implement
20 such change or changes and shall report
21 such changes or changes to the Secretary
22 within 30 days.

23 “(ii) CONTENT.—Any report to the
24 Secretary under this subparagraph shall
25 include—

1 “(I) a summary of the relevant
2 change or changes;

3 “(II) the rationale for imple-
4 menting such change or changes;

5 “(III) a description of how the
6 change or changes were evaluated;
7 and

8 “(IV) data indicating analytical
9 and clinical validity.

10 “(iii) SUPPLEMENTAL REPORTS.—
11 Upon review of such report and a finding
12 that the relevant change or changes are in-
13 consistent with the standard specified
14 under this subparagraph, the Secretary
15 may require a supplement under subpara-
16 graph (A).

17 “(h) MAINTENANCE REQUIREMENTS.—For the dura-
18 tion of a technology certification order, a holder of a tech-
19 nology certification order shall—

20 “(1) use the procedures included in the relevant
21 application, supplement, or report under subsections
22 (b) and (e);

23 “(2) ensure compliance with any applicable
24 mitigating measures;

1 “(3) maintain, and provide to the Secretary
2 upon request, records related to any in vitro clinical
3 test offered under the technology certification order,
4 where those records are necessary to demonstrate
5 compliance with applicable provisions of this sub-
6 chapter; and

7 “(4) comply with the listing requirements under
8 section 587I for each in vitro clinical test offered
9 under the technology certification order.

10 “(i) TEMPORARY HOLD.—

11 “(1) IN GENERAL.—Upon one or more findings
12 under paragraph (4) and after promptly notifying
13 the developer of such findings, the Secretary may
14 issue a temporary hold prohibiting any holder of a
15 technology certification order from introducing into
16 interstate commerce an in vitro clinical test that was
17 not previously the subject of a notification under
18 section 587I. The temporary hold must identify the
19 grounds for the temporary hold under paragraph (4)
20 and the rationale for such finding, and may only re-
21 main in place until the Secretary responds to a writ-
22 ten request under paragraph (3).

23 “(2) NOTIFICATION TO THE DEVELOPER.—The
24 Secretary shall not place a temporary hold under
25 this subsection unless the Secretary has promptly

1 notified the developer of such hold and provided 30
2 calendar days for the developer to come into compli-
3 ance with or resolve the findings under paragraph
4 (4).

5 “(3) WRITTEN REQUESTS.—Any written re-
6 quest to the Secretary from the holder of a tech-
7 nology certification order that a temporary hold
8 under paragraph (1) be removed shall receive a deci-
9 sion, in writing and specifying the reasons therefore,
10 within 90 days after receipt of such request. Any
11 such request shall include information to support the
12 removal of the temporary hold.

13 “(4) GROUNDS FOR TEMPORARY HOLD.—A
14 temporary hold under this subsection may be
15 instated upon a finding or findings that the holder
16 of a technology certification order—

17 “(A) is not in compliance with any mainte-
18 nance requirements under subsection (h);

19 “(B) labels or advertises one or more in
20 vitro clinical tests with false or misleading
21 claims; or

22 “(C) is no longer an eligible person under
23 subsection (b)(1).

24 “(j) WITHDRAWAL.—The Secretary may, after due
25 notice and opportunity for informal hearing, issue an

1 order withdrawing a technology certification order if the
2 Secretary finds that—

3 “(1) the application, supplement, or report
4 under subsection (e) or (g) contains materially false
5 or misleading information or fails to reveal a mate-
6 rial fact;

7 “(2) such holder fails to correct materially false
8 or misleading labeling or advertising upon the re-
9 quest of the Secretary;

10 “(3) in connection with a technology certifi-
11 cation, the holder provides materially false or mis-
12 leading information to the Secretary; or

13 “(4) the holder of such technology certification
14 order fails to correct the grounds for temporary hold
15 within a timeframe specified in the temporary hold
16 order.

17 “(k) REPORTS TO CONGRESS.—

18 “(1) IN GENERAL.—Not later than one year
19 after date of enactment of the Verifying Accurate
20 Leading-edge IVCT Development Act of 2021, and
21 annually thereafter for the next 4 years, the Sec-
22 retary shall submit to the Committee on Energy and
23 Commerce of the House of Representatives and the
24 Committee on Health, Education, Labor, and Pen-
25 sions of the Senate, and make publicly available, in-

1 cluding through posting on the website of the Food
2 and Drug Administration, a report containing the
3 information described in paragraph (2).

4 “(2) CONTENT.—

5 “(A) IN GENERAL.—Each report under
6 paragraph (1) shall address, at a minimum—

7 “(i) the total number of applications
8 for technology certifications filed, granted,
9 withdrawn and denied;

10 “(ii) the total number of technology
11 certification orders put on temporary hold
12 under subsection (i) and the number of
13 technology certification orders withdrawn
14 under subsection (j);

15 “(iii) the types of technologies for
16 which technology certification orders were
17 granted;

18 “(iv) the total number of developers,
19 including laboratories, with technology cer-
20 tification orders in effect; and

21 “(v) the total number of approved
22 tests under section 587B that were reclas-
23 sified and granted a technology certifi-
24 cation order under this section.

1 “(B) FINAL REPORT.—The fifth report
2 submitted under paragraph (1) shall include a
3 summary of, and responses to, comments raised
4 in the meeting and docket.

5 “(C) PERFORMANCE REPORTS.—The re-
6 ports required under this section may be issued
7 with performance reports as required under sec-
8 tion 9 of the Verifying Accurate Leading-edge
9 IVCT Development Act of 2021.

10 **“SEC. 587E. MITIGATING MEASURES.**

11 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

12 “(1) ESTABLISHING, CHANGING, OR WITH-
13 DRAWING.—

14 “(A) ESTABLISHMENT.—If the Secretary
15 requires the establishment of mitigating meas-
16 ures pursuant to clause (i) or (ii) of section
17 587(15)(A) for any in vitro clinical test, the
18 Secretary may require such mitigating meas-
19 ures for any other in vitro clinical test with the
20 same indications for use.

21 “(B) PROCESS.—Notwithstanding sub-
22 chapter II of chapter 5 of title 5, United States
23 Code, the Secretary may—

24 “(i) establish, change, or withdraw
25 mitigating measures by—

1 “(I) publishing a proposed ad-
2 ministrative order in the Federal Reg-
3 ister;

4 “(II) providing an opportunity
5 for public comment for a period of not
6 less than 30 calendar days; and

7 “(III) after consideration of any
8 comments submitted, publishing a
9 final administrative order in the Fed-
10 eral Register; and

11 “(ii) may establish mitigating meas-
12 ures with respect to a category in a pre-
13 market approval order or technology cer-
14 tification order.

15 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
16 APPROVED, CLEARED, OR EXEMPTED AS DEVICES.—

17 “(A) IN GENERAL.—Any special controls
18 or restrictions applicable to an in vitro clinical
19 test with the same indications for use pursuant
20 to section 587(10) based on prior regulation as
21 a device approved under section 515, cleared or
22 exempt under section 510(k), or classified
23 under section 513(f)(2), including any such spe-
24 cial controls or restrictions established during
25 the period beginning on the date of enactment

1 of the Verifying Accurate Leading-edge IVCT
2 Development Act of 2021 and ending on the ef-
3 fective date of such Act (as described in section
4 5(b) of such Act)—

5 “(i) shall continue to apply to such
6 approved, cleared, or exempted in vitro
7 clinical test after such effective date; and

8 “(ii) are deemed to be mitigating
9 measures as of the effective date of such
10 approval, clearance, or exemption.

11 “(B) CHANGES.—The Secretary may es-
12 tablish, change, or withdraw mitigating meas-
13 ures for such a test or indications for use the
14 procedures under paragraph (1).

15 “(b) DOCUMENTATION.—

16 “(1) TESTS SUBJECT TO PREMARKET RE-
17 VIEW.—The developer of an in vitro clinical test sub-
18 ject to premarket review under section 587B and to
19 which mitigating measures apply shall—

20 “(A) in accordance with section
21 587B(c)(2)(G)(i), submit documentation to the
22 Secretary as part of the application for the test
23 under subsection (c) or (d) of section 587B
24 demonstrating that such mitigating measures
25 have been met;

1 “(B) if such application is approved, main-
2 tain documentation demonstrating that such
3 mitigating measures continue to be met fol-
4 lowing a test modification by the developer; and

5 “(C) after responding to any informal com-
6 munications from the Secretary, make such
7 documentation available to the Secretary upon
8 request or inspection.

9 “(2) OTHER TESTS.—The developer of an in
10 vitro clinical test that is marketed within the scope
11 of a technology certification order or other exemp-
12 tion from premarket review under section 587B and
13 to which mitigating measures apply shall—

14 “(A) maintain documentation in accord-
15 ance with the applicable quality requirements
16 under section 587J demonstrating that such
17 mitigating measures continue to be met fol-
18 lowing a test modification by the developer;

19 “(B) after responding to any informal
20 communications from the Secretary, make such
21 documentation available to the Secretary upon
22 request or inspection; and

23 “(C) include in the performance summary
24 for such test a brief description of how such
25 mitigating measures are met, if applicable.

1 “(c) MITIGATING MEASURES FOR CROSS-REF-
2 ERENCED TESTS.—Not later than 1 year after the imple-
3 mentation of the Verifying Accurate Leading-edge IVCT
4 Development Act of 2021, the Secretary shall issue miti-
5 gating measures for cross-referenced tests.

6 **“SEC. 587F. REGULATORY PATHWAY REDESIGNATION.**

7 “(a) TECHNOLOGY CERTIFICATION AND EXEMPTION
8 DETERMINATIONS.—

9 “(1) IN GENERAL.—Based on new information,
10 including the establishment of mitigating measures
11 under section 587E, and after considering available
12 evidence respecting tests with the same indications
13 for use pursuant to section 587(10), the Secretary
14 may, upon the initiative of the Secretary or upon pe-
15 tition of an interested person—

16 “(A) revoke any exemption or requirement
17 in effect under this subchapter with respect to
18 such indications for use; or

19 “(B) determine that such indications for
20 use are eligible for technology certification in
21 accordance with section 587D(b)(2).

22 “(2) PROCESS.—Any action under paragraph
23 (1) shall be made by publication of a notice of such
24 proposed action on the website of the Food and
25 Drug Administration, the consideration of comments

1 to a public docket on such proposal, and publication
2 of a final action on such website within 60 calendar
3 days of the close of the comment period posted to
4 such public docket, notwithstanding subchapter II of
5 chapter 5 of title 5, United States Code.

6 “(b) REVOCATION.—The Secretary may revoke any
7 exemption with respect to such test or indications for use
8 pursuant to section 587(10), if—

9 “(1) new clinical information indicates that the
10 exemption of an in vitro clinical test or tests from
11 premarket review under section 587B or exemption
12 under section 587A has a reasonable probability of
13 severe adverse health consequences, including the
14 absence, delay, or discontinuation of appropriate
15 medical treatment.

16 “(2) PROCESS.—Any action under this sub-
17 section shall be made by publication of a notice of
18 such proposed action in the Federal Register, con-
19 sideration of comments to a public docket on such
20 proposal, and publication of a final notice in the
21 Federal Register, notwithstanding subchapter II of
22 chapter 5 of title 5, United States Code.

23 **“SEC. 587G. ADVISORY COMMITTEES.**

24 “(a) IN GENERAL.—The Secretary may establish ad-
25 visory committees or use advisory committee panels of ex-

1 perts established before the date of enactment of this sec-
2 tion for the purposes of providing expert scientific advice
3 and making recommendations related to—

4 “(1) the approval of an application for an in
5 vitro clinical test submitted under this subchapter,
6 including for evaluating, as applicable, the analytical
7 validity, clinical validity, and safety of in vitro clin-
8 ical tests;

9 “(2) the potential effectiveness of mitigating
10 measures for a determination on the applicable regu-
11 latory pathway under section 587F or risk evalua-
12 tion for an in vitro clinical test or tests;

13 “(3) quality requirements under section 587J
14 or applying such requirements to in vitro clinical
15 tests developed or imported by developers; or

16 “(4) such other purposes as the Secretary de-
17 termines appropriate.

18 “(b) APPOINTMENTS.—

19 “(1) VOTING MEMBERS.—The Secretary shall
20 appoint to each committee established under sub-
21 section (a), as voting members, individuals who are
22 qualified by training and experience to evaluate in
23 vitro clinical tests referred to the committee for the
24 purposes specified in subsection (a), including indi-
25 viduals with, to the extent feasible, scientific exper-

1 tise in the development, manufacture, or utilization
2 of such in vitro clinical tests, laboratory operations,
3 and the use of in vitro clinical tests. The Secretary
4 shall designate one member of each committee to
5 serve as chair.

6 “(2) NONVOTING MEMBERS.—In addition to the
7 individuals appointed pursuant to paragraph (1), the
8 Secretary shall appoint to each committee estab-
9 lished under subsection (a), as nonvoting members—

10 “(A) a representative of consumer inter-
11 ests; and

12 “(B) a representative of interests of in
13 vitro clinical test developers not directly af-
14 fected by the matter to be brought before the
15 committee.

16 “(3) LIMITATION.—No individual who is in the
17 regular full-time employee of the United States and
18 engaged in the administration of this Act may be a
19 member of any advisory committee established under
20 subsection (a).

21 “(4) EDUCATION AND TRAINING.—The Sec-
22 retary shall, as appropriate, provide education and
23 training to each new committee member before such
24 member participates in a committee’s activities, in-
25 cluding education regarding requirements under this

1 Act and related regulations of the Secretary, and the
2 administrative processes and procedures related to
3 committee meetings.

4 “(5) MEETINGS.—The Secretary shall ensure
5 that scientific advisory committees meet regularly
6 and at appropriate intervals so that any matter to
7 be reviewed by such a committee can be presented
8 to the committee not more than 60 calendar days
9 after the matter is ready for such review. Meetings
10 of the committee may be held using electronic com-
11 munication to convene the meetings.

12 “(6) COMPENSATION.—Members of an advisory
13 committee established under subsection (a), while at-
14 tending meetings or conferences or otherwise en-
15 gaged in the business of the advisory committee—

16 “(A) shall be entitled to receive compensa-
17 tion at rates to be fixed by the Secretary, but
18 not to exceed the daily equivalent of the rate in
19 effect for positions classified above level GS-15
20 of the General Schedule; and

21 “(B) may be allowed travel expenses as au-
22 thorized by section 5703 of title 5, United
23 States Code, for employees serving intermit-
24 tently in the Government service.

1 “(c) GUIDANCE.—The Secretary may issue guidance
2 on the policies and procedures governing advisory commit-
3 tees established under subsection (a).

4 **“SEC. 587H. REQUEST FOR INFORMAL FEEDBACK.**

5 “Before submitting a premarket application or tech-
6 nology certification application for an in vitro clinical
7 test—

8 “(1) the developer of the test may submit to the
9 Secretary a written request for a meeting, con-
10 ference, or written feedback to discuss and provide
11 information relating to the regulation of such in
12 vitro clinical test which may include—

13 “(A) the submission process and the type
14 and amount of evidence expected to dem-
15 onstrate the applicable standard;

16 “(B) which regulatory pathway is appro-
17 priate for an in vitro clinical test; and

18 “(C) an investigation plan for an in vitro
19 clinical test, including a clinical protocol; and

20 “(2) upon receipt of such a request, the Sec-
21 retary shall—

22 “(A) within 60 calendar days after such
23 receipt, or within such time period as may be
24 agreed to by the developer, meet or confer with
25 the developer submitting the request; and

1 “(B) within 15 calendar days after such
2 meeting or conference, provide to the developer
3 a written record or response describing the
4 issues discussed and conclusions reached in the
5 meeting or conference.

6 **“SEC. 587I. REGISTRATION AND LISTING.**

7 “(a) REGISTRATION OF ESTABLISHMENTS FOR IN
8 VITRO CLINICAL TESTS.—

9 “(1) IN GENERAL.—Each person described in
10 subsection (b)(1), or an accredited person under sec-
11 tion 587P, acting on behalf of such a person, shall—

12 “(A) during the period beginning on Octo-
13 ber 1 and ending on December 31 of each year,
14 register with the Secretary the name of such
15 person, places of business of such person, all es-
16 tablishments engaged in the activities specified
17 under this paragraph, the establishment reg-
18 istration number of each such establishment,
19 and a point of contact for each such establish-
20 ment, including an electronic point of contact;
21 and

22 “(B) submit an initial registration con-
23 taining the information required under subpara-
24 graph (A) not later than—

1 “(i) the date of implementation of this
2 section if such establishment is engaged in
3 any activity described in subsection (b)(1)
4 on the date of enactment of this section,
5 unless the Secretary establishes by guid-
6 ance a date later than such implementation
7 date for all or a category of such establish-
8 ments; or

9 “(ii) 30 days prior to engaging in any
10 activity described in subsection (b)(1) after
11 enactment of this section, if such establish-
12 ment is not engaged in any activity de-
13 scribed in this paragraph on the date of
14 enactment of this section.

15 “(2) REGISTRATION NUMBERS.—The Secretary
16 may assign a registration number to any person or
17 an establishment registration number to any estab-
18 lishment registered in accordance with this section.
19 Registration information shall be made publicly
20 available by publication on the website maintained
21 by the Food and Drug Administration, in accord-
22 ance with subsection (d).

23 “(3) INSPECTION.—Each person or establish-
24 ment that is required to be registered with the Sec-

1 retary under this section shall be subject to inspec-
2 tion pursuant to section 704.

3 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL
4 TESTS.—

5 “(1) IN GENERAL.—Each person who—

6 “(A) is a developer, a contract manufac-
7 turer (including contract packaging), contract
8 sterilizer, repackager, relabeler, or distributor of
9 an in vitro clinical test; and

10 “(B) introduces or proposes to begin the
11 introduction or delivery for introduction into
12 interstate commerce through an exemption
13 under section 587A(f)(2)(b) or 587A(g) or
14 through the filing of an application under sec-
15 tion 587B or 587D,

16 shall submit a listing to the Secretary containing the
17 information described in paragraph (2) in accord-
18 ance with the applicable schedule described under
19 subsection (c). Such listing shall be prepared in such
20 form and manner as the Secretary may specify in
21 guidance. Listing information shall be submitted
22 through the comprehensive test information system
23 in accordance with section 587T, as appropriate.

24 “(2) SUBMISSIONS.—Each developer submitting
25 a listing under paragraph (1) shall electronically

1 submit to the comprehensive test information system
2 under section 587T the following information for
3 each in vitro clinical test for which such person is
4 a developer in the form and manner prescribed by
5 the Secretary:

6 “(A) Name of the establishment and its es-
7 tablishment registration number.

8 “(B) Contact information for the official
9 correspondent for the listing.

10 “(C) Name (common name and trade
11 name, if applicable) of the in vitro clinical test
12 and its test listing number (when available).

13 “(D) CLIA certificate number for any lab-
14 oratory certified by the Secretary under section
15 353 of the Public Health Service Act that
16 meets the requirements for performing high-
17 complexity testing that is the developer of the
18 in vitro clinical test, and CLIA certificate num-
19 ber for any laboratory under common ownership
20 that is performing the test developed by such
21 test developer.

22 “(E) Whether the in vitro clinical test is,
23 as applicable, offered as a test approved under
24 section 587B, offered under a technology cer-
25 tification o, or offered as an in vitro clinical test

1 under section 587Arder issued under section
2 587D.

3 “(F) Indications for use information under
4 section 587(10).

5 “(G) Brief narrative description of the in
6 vitro clinical test.

7 “(H) A brief summary of the analytical
8 and clinical performance of the in vitro clinical
9 test, and as applicable, the lot release criteria.

10 “(I) A brief description of conformance
11 with any applicable mitigating measures, re-
12 strictions, and standards.

13 “(J) Representative labeling for the in
14 vitro clinical test, as appropriate.

15 “(K) A statement that the information
16 submitted is truthful and accurate.

17 “(3) TEST LISTING NUMBER.—The Secretary
18 may assign a test listing number to each in vitro
19 clinical test that is the subject of a listing under this
20 section. The process for assigning test listing num-
21 bers may be established through guidance, and may
22 include the recognition of standards, formats, or
23 conventions developed by a third-party organization.

24 “(4) ABBREVIATED LISTING.—A person who is
25 not a developer but is otherwise required to register

1 pursuant to subsection (a) shall submit an abbreve-
2 viated listing to the Secretary containing the infor-
3 mation described in subparagraphs (A) through (C)
4 of paragraph (2), and the name of the developer.
5 The information shall be submitted in accordance
6 with the applicable schedule described under sub-
7 section (c). Such abbreviated listing shall be pre-
8 pared in such form and manner as the Secretary
9 may specify in guidance. Listing information shall be
10 submitted to the comprehensive test information sys-
11 tem in accordance with section 587T, as appro-
12 priate.

13 “(5) GRANDFATHERED TESTS.—A developer of
14 an in vitro clinical test developer offering a test that
15 is grandfathered under section 587A(c) shall submit
16 listing information required under subparagraphs
17 (A) through (K) of paragraph (2).

18 “(6) LOW-RISK TESTS.—A developer of a low
19 risk in vitro clinical test shall notify and submit list-
20 ing information to the Secretary within one year of
21 offering such test for clinical use.

22 “(7) EXEMPT TESTS.—A developer of an in
23 vitro clinical test who introduces or proposes to
24 begin the introduction or delivery for introduction
25 into interstate commerce pursuant to an exemption

1 under section 587A may submit listing information
2 under this subsection.

3 “(c) TIMELINES FOR SUBMISSION.—

4 “(1) IN GENERAL.—The timelines for submis-
5 sion of registration and listing under subsections (a)
6 and (b) are as follows:

7 “(A) For an in vitro clinical test that was
8 listed as a device under section 510(j) prior to
9 the date of enactment of this section, a person
10 shall maintain a device listing under section
11 510 until such time as the system for submit-
12 ting the notification information required under
13 subsection (b) becomes available and thereafter
14 shall submit the notification information no
15 later than 1 year after the system for submit-
16 ting the notification under this section becomes
17 available.

18 “(B) For an in vitro clinical test that is
19 subject to the grandfathering provisions of sec-
20 tion 587A(c), a person shall submit the listing
21 information required under subsection (b)(5) no
22 later than 1 year after the system for submit-
23 ting the notification under this section becomes
24 available.

1 “(C) For an in vitro clinical test that is
2 not described in subparagraph (A) or (B), a
3 person shall submit the required notification in-
4 formation prior to offering, introducing, or mar-
5 keting the in vitro clinical test as follows:

6 “(i) For an in vitro clinical test that
7 is not exempt from premarket approval
8 under section 587B, a person shall submit
9 the required listing information no later
10 than 30 business days after the date of ap-
11 proval of the premarket approval applica-
12 tion.

13 “(ii) For a developer who has received
14 a technology certification order under sec-
15 tion 587D, a person shall submit the re-
16 quired listing information at least 30 busi-
17 ness days after receiving such technology
18 certification order.

19 “(2) UPDATES.—

20 “(A) UPDATES AFTER CHANGES.—Each
21 developer required to submit listing information
22 under this section shall update such informa-
23 tion within 10 business days of any change that
24 causes any previously notified information to be
25 inaccurate or incomplete.

1 “(B) ANNUAL UPDATES.—Each developer
2 required to submit listing information under
3 this section shall update its information annu-
4 ally during the period beginning on October 1
5 and ending on December 31 of each year as a
6 component of the annual report submitted
7 under sections 587B and 587D.

8 “(d) PUBLIC AVAILABILITY OF NOTIFICATION IN-
9 FORMATION.—

10 “(1) IN GENERAL.—Notification information
11 submitted pursuant to this section shall be made
12 publicly available on the website of the Food and
13 Drug Administration in accordance with paragraph
14 (3).

15 “(2) CONFIDENTIALITY.—Notification informa-
16 tion for an in vitro clinical test that is subject to
17 premarket approval or technical certification shall
18 remain confidential until such date as the in vitro
19 clinical test receives the applicable premarket ap-
20 proval or the developer receives a technology certifi-
21 cation order.

22 “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY
23 REQUIREMENTS.—The registration and listing infor-
24 mation requirements described in subsections (a)

1 and (b) shall not apply to the extent the Secretary
2 determines that such information relates to—

3 “(A) trade secret or commercial confiden-
4 tial information; or

5 “(B) national security or countermeasures
6 or is restricted from disclosure pursuant to an-
7 other provision of law.

8 “(e) SUBMISSION OF INFORMATION BY ACCREDITED
9 PERSONS.—If agreed upon by the developer, the informa-
10 tion required under this section may be submitted by an
11 accredited person under section 587P.

12 **“SEC. 587J. TEST DESIGN AND QUALITY REQUIREMENTS.**

13 “(a) APPLICABILITY.—

14 “(1) IN GENERAL.—Each developer and each
15 other person required to register under section
16 587I(b)(1) shall establish and maintain quality re-
17 quirements in accordance with the applicable re-
18 quirements set forth in subsection (b), except as pro-
19 vided in section 587A.

20 “(2) CERTIFIED LABORATORY REQUIRE-
21 MENTS.—A developer that operates a clinical labora-
22 tory certified by the Secretary under section 353 of
23 the Public Health Service Act that—

24 “(A) meets the requirements for per-
25 forming high-complexity testing;

1 “(B)(i) develops an vitro clinical test or in-
2 dications for use; or

3 “(ii) modifies another developer’s in vitro
4 clinical test in that certified laboratory in a
5 manner described in section 587(6)(C); and

6 “(C) develops an in vitro clinical test or in-
7 dications for use that are for use only within
8 that certified laboratory or within another cer-
9 tified laboratory with common ownership,
10 shall establish and maintain quality requirements
11 that comply with the requirements set forth in sub-
12 section (b)(2).

13 “(3) APPLICABILITY FOR CERTAIN IN VITRO
14 CLINICAL TESTS.—The applicable requirements set
15 forth in subsection (b)(1) shall apply to any instru-
16 ment, specimen receptacle, or component or part
17 that is developed for use by a clinical laboratory to
18 which paragraph (2) applies.

19 “(4) REGULATIONS.—In promulgating regula-
20 tions under this section, the Secretary shall consider
21 whether and to what extent international harmoni-
22 zation is appropriate.

23 “(b) QUALITY REQUIREMENTS.—

24 “(1) QUALITY REQUIREMENTS FOR LABORA-
25 TORIES WITHOUT CLIA CERTIFICATION TO CONDUCT

1 HIGH-COMPLEXITY TESTS.—The quality require-
2 ments applicable under this section shall—

3 “(A) avoid duplication of regulations under
4 section 353 of the Public Health Service Act;

5 “(B) apply only to the development, valida-
6 tion, production, preparation, propagation, or
7 assembly related to the design and associated
8 manufacture and distribution of an in vitro clin-
9 ical test offered under this subchapter;

10 “(C) not apply with respect to laboratory
11 operations; and

12 “(D) shall include the following, subject to
13 paragraphs (2) and (3)—

14 “(i) management responsibility;

15 “(ii) quality audits;

16 “(iii) personnel;

17 “(iv) design controls;

18 “(v) document controls;

19 “(vi) purchasing controls;

20 “(vii) identification and traceability;

21 “(viii) production and process con-
22 trols;

23 “(ix) acceptance activities;

24 “(x) nonconforming product;

25 “(xi) corrective and preventive action;

- 1 “(xii) labeling and packaging controls;
2 “(xiii) handling, storage, distribution,
3 and installation;
4 “(xiv) records;
5 “(xv) servicing; and
6 “(xvi) statistical techniques.

7 “(2) QUALITY REQUIREMENTS FOR LABORA-
8 TORIES CERTIFIED TO CONDUCT HIGH-COMPLEXITY
9 TESTS.—Quality requirements applicable to the in
10 vitro clinical tests and developers described in sub-
11 section (a)(2) shall—

12 “(A) avoid duplication of regulations under
13 section 353 of the Public Health Service Act;
14 and

15 “(B) consist of, as directed related to the
16 design and development—

- 17 “(i) design controls;
18 “(ii) purchasing controls;
19 “(iii) acceptance activities;
20 “(iv) corrective and preventative ac-
21 tion; and
22 “(v) records.

23 “(3) QUALITY REQUIREMENTS FOR CERTAIN
24 LABORATORIES DISTRIBUTING IN VITRO CLINICAL

1 TESTS OR TEST PROTOCOLS WITHIN ORGANIZATIONS
2 OR PUBLIC HEALTH NETWORKS.—

3 “(A) IN GENERAL.—Quality requirements
4 applicable to the developer who is distributing
5 in vitro clinical test distributed as described in
6 subparagraph (B) shall consist of the following:

7 “(i) The requirements in paragraph
8 (2).

9 “(ii) The labeling requirements in
10 paragraph (1)(C)(xii).

11 “(iii) The requirement to maintain
12 records of the laboratories to which the in
13 vitro clinical test or test protocol is distrib-
14 uted.

15 “(B) DISTRIBUTING LABORATORY.—Sub-
16 paragraph (A) shall apply to developers that
17 meet the following conditions:

18 “(i) The laboratory distributing the
19 test protocol is certified by the Secretary
20 under section 353 of the Public Health
21 Service Act and meets the requirements for
22 performing high-complexity testing.

23 “(ii) The laboratory develops its own
24 in vitro clinical test or modifies another de-

1 developer’s in vitro clinical test in a manner
2 described in section 587(6)(C).

3 “(iii) The laboratory distributes the in
4 vitro clinical test or test protocol for such
5 test only to another laboratory that—

6 “(I) is certified by the Secretary
7 under section 353 of the Public
8 Health Service Act and meets the re-
9 quirements for performing high-com-
10 plexity testing;

11 “(II) is within the same cor-
12 porate organization and having com-
13 mon ownership by the same parent
14 corporation; or as applicable, is a lab-
15 oratory within a public health labora-
16 tory network coordinated or managed
17 by the Centers for Disease Control
18 and Prevention; and

19 “(III) implements the test pro-
20 tocol without further modification.

21 “(c) REGULATIONS.—In implementing quality re-
22 quirements for test developers under this section, the Sec-
23 retary shall—

24 “(1) for purposes of facilitating international
25 harmonization, consider whether the developer par-

1 participates in an audit program in which the United
2 States participates or the United States recognizes
3 or conforms with standards recognized by the Sec-
4 retary; and

5 “(2) ensure a least burdensome approach de-
6 scribed in section 587B(j) by leveraging, to the ex-
7 tent applicable, the quality assurance requirements
8 applicable to developers certified by the Secretary
9 under section 353 of the Public Health Service Act.

10 **“SEC. 587K. LABELING REQUIREMENTS.**

11 “(a) IN GENERAL.—An in vitro clinical test shall
12 bear or be accompanied by labeling, and a label as applica-
13 ble, that meet the requirements set forth in subsections
14 (b) and (c), unless such test is exempt as specified in sub-
15 section (d) or (e).

16 “(b) LABELS.—

17 “(1) IN GENERAL.—The label of an in vitro
18 clinical test shall meet the requirements set forth in
19 paragraph (2), except this requirement shall not
20 apply to an in vitro clinical test that—

21 “(A) consists solely of a test protocol; or

22 “(B) is developed, manufactured, and used
23 solely within a single laboratory certified by the
24 Secretary under section 353 of the Public

1 Health Service Act that meets the requirements
2 for performing high-complexity testing.

3 “(2) REGULATIONS.—The label of an in vitro
4 clinical test shall state the name and place of busi-
5 ness of its developer and meet the requirements set
6 forth in regulations promulgated under this section.

7 “(c) LABELING.—

8 “(1) IN GENERAL.—Labeling accompanying an
9 in vitro clinical test, including labeling in the form
10 of a package insert, standalone laboratory reference
11 document, or other similar document except the la-
12 beling specified in paragraph (2), shall include ade-
13 quate directions for use and shall meet the require-
14 ments set forth in regulations promulgated under
15 this section, except as provided in subsection (d) or
16 (e).

17 “(2) CONTENT.—

18 “(A) IN GENERAL.—Labeling accom-
19 panying an in vitro clinical test that is in the
20 form of a test report template or ordering infor-
21 mation shall include—

22 “(i) the test listing number that was
23 provided to the developer at the time of
24 listing;

1 “(ii) instructions for how and where
2 to report an adverse event under section
3 587L;

4 “(iii) instructions for how and where
5 to access the performance summary data
6 displayed in the listing database for the
7 test;

8 “(iv) the intended use of the in vitro
9 clinical test; and

10 “(v) any warnings, contraindications,
11 or limitations.

12 “(B) PUBLIC AVAILABILITY OF INFORMA-
13 TION.—The Secretary shall make all of the in-
14 formation described in subparagraph (A) with
15 respect to each in vitro clinical test available to
16 the public, as applicable, in accordance with
17 section 587T, except to the extent that the Sec-
18 retary determines that such information is—

19 “(i) trade secret or commercial con-
20 fidential information; or

21 “(ii) national security or counter-
22 measures or is restricted from disclosure
23 pursuant to another provision of law.

24 “(3) ADDITIONAL REQUIREMENTS.—Labeling
25 for an in vitro clinical test used for

1 immunohematology testing shall meet the applicable
2 requirements set forth in part 660 of title 21, Code
3 of Federal Regulations (or any successor regula-
4 tions), related to the labeling of blood grouping re-
5 agents, reagent red blood cells, and anti-human
6 globulin.

7 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
8 MENTS.—

9 “(1) IN GENERAL.—

10 “(A) IN GENERAL.—With respect to an in
11 vitro clinical test that meets the criteria of sub-
12 paragraph (B), the ‘state in one place’ regula-
13 tions under section 809.10(b) of title 21 of the
14 Code of Federal Regulations (or any successor
15 regulations) may be satisfied by the laboratory
16 posting such information on its website or in
17 multiple documents, if such documents are
18 maintained and accessible in one place.

19 “(B) APPLICABLE TESTS.—An in vitro
20 clinical test meets the criteria of this subpara-
21 graph if such test is—

22 “(i) designed and manufactured by a
23 laboratory certified by the Secretary under
24 section 353 of the Public Health Service

1 Act that meets the requirements for per-
2 forming high-complexity testing; and

3 “(ii) performed in the same laboratory
4 in which it was developed or by another
5 such laboratory certified by the Secretary
6 under section 353 of the Public Health
7 Service Act that meets the requirements
8 for performing high complexity testing and
9 is under common ownership with the lab-
10 oratory that designed and manufactured
11 the test.

12 “(2) TEST INSTRUMENT LABELING.—The label-
13 ing for an instrument is not required to bear the in-
14 formation indicated in paragraphs (3), (4), (5), (7),
15 (8), (9), (10), (11), (12), and (13) of section
16 809.10(b) of title 21 of the Code of Federal Regula-
17 tions (or any successor regulations).

18 “(3) REAGENT LABELING.—For purposes of
19 compliance with subsection (c)(1), the labeling for a
20 reagent intended for use as a replacement in an in
21 vitro clinical test may be limited to that information
22 necessary to identify the reagent adequately and to
23 describe its proper use in the system.

24 “(4) LAB RESEARCH OR INVESTIGATIONAL
25 USE.—A shipment or other delivery of an in vitro

1 clinical test for research or investigational use pur-
2 suant to section 587A(m) shall be exempt from the
3 labeling requirements of subsections (b) and (c)(1)
4 and from any standard promulgated through regula-
5 tions, except as required under section 353 of the
6 Public Health Service Act or section 587R of this
7 Act.

8 “(5) GENERAL PURPOSE LABORATORY RE-
9 AGENTS.—The labeling of general purpose labora-
10 tory reagents (such as hydrochloric acid) whose uses
11 are generally known by persons trained in their use
12 need not bear the directions for use required by sub-
13 sections (b) and (c)(1).

14 “(6) ANALYTE SPECIFIC REAGENTS.—The la-
15 beling for analyte specific reagents shall bear the fol-
16 lowing statement: ‘This product is intended solely
17 for further development of an in vitro clinical test
18 and is exempt from most FDA regulation. This
19 product must be evaluated by the in vitro clinical
20 test developer in accordance with applicable require-
21 ments.’. If the labeling of an analyte specific reagent
22 bears the statement set forth in this paragraph, it
23 need not bear the information required by subsection
24 (c)(1).

1 “(7) OVER-THE-COUNTER TEST SAMPLE COL-
2 LECTION SYSTEMS LABELING.—The labeling for
3 over-the-counter test sample collection systems for
4 drugs of abuse testing shall bear the name and place
5 of business of the developer included in the registra-
6 tion listing under section 587I, in language appro-
7 priate for the intended users.

8 “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-
9 PILE.—

10 “(1) IN GENERAL.—The Secretary may grant
11 an exception or alternative to any provision listed in
12 this section, unless explicitly required by a statutory
13 provision outside this subchapter, for specified lots,
14 batches, or other units of an in vitro clinical test, if
15 the Secretary determines that compliance with such
16 labeling requirement could adversely affect the safe-
17 ty, effectiveness, or availability of such products that
18 are or will be included in the Strategic National
19 Stockpile under section 319F–2 of the Public Health
20 Service Act.

21 “(2) REGULATIONS.—The Secretary may issue
22 regulations amending section 809.11 of title 21 of
23 the Code of Federal Regulations or any successor
24 regulation to apply in full or in part to in vitro clin-
25 ical tests and in vitro clinical test developers.

1 “(f) GUIDANCE.—The Secretary may, in collabora-
2 tion with developers, issue guidance on standardized, gen-
3 eral content and format for in vitro clinical test labeling
4 to help ensure compliance with applicable requirements in
5 this subsection.

6 **“SEC. 587L. ADVERSE EVENT REPORTING.**

7 “(a) APPLICABILITY.—

8 “(1) IN GENERAL.—Each in vitro clinical test
9 developer shall establish and maintain a system for
10 reporting adverse events in accordance with sub-
11 section (b), except as provided in section 587A.

12 “(2) REGULATIONS.—The Secretary shall pro-
13 mulgate regulations to implement this section, in-
14 cluding information necessary to be reported to en-
15 sure the analytical and clinical validity of in vitro
16 clinical tests, and the safety of articles for taking or
17 deriving specimens from the human body.

18 “(b) ADVERSE EVENT REPORTING REQUIRE-
19 MENTS.—Each developer shall report to the Secretary
20 whenever information that reasonably suggests that one
21 of the developer’s in vitro clinical tests is associated with
22 an adverse event becomes known to the developer.

23 “(c) REPORTS.—Reports required under this section
24 shall be submitted as follows:

1 “(1) An individual adverse event report shall be
2 submitted for the following events not later than—

3 “(A) 5 calendar days after an in vitro clin-
4 ical test developer receives or otherwise becomes
5 aware of information that reasonably suggests
6 the adverse event involves a patient death; or

7 “(B) 5 calendar days after an in vitro clin-
8 ical test developer receives or otherwise becomes
9 aware of information that reasonably suggests
10 the event presents an imminent threat to public
11 health.

12 “(2) Quarterly reports shall be submitted for all
13 other adverse events, if any, and no later than the
14 end of the quarter following the quarter in which the
15 adverse event information was received by the in
16 vitro clinical test developer.

17 “(d) DEFINITIONS.—In this section—

18 “(1) the term ‘adverse event’—

19 “(A) means—

20 “(i) death of, or serious injury to, a
21 specific patient or user for which it is rea-
22 sonably believed that an in vitro clinical
23 test error contributed to such death or se-
24 rious injury; or

1 “(ii) an in vitro clinical test error that
2 may have reasonable likelihood to cause se-
3 rious injury or death; and

4 “(B) excludes laboratory errors that are
5 subject to the requirements of section 353 of
6 the Public Health Service Act and corrective or
7 preventive actions to prevent such errors;

8 “(2) the term ‘in vitro clinical test error’—

9 “(A) means a failure in an in vitro clinical
10 test to meet the analytical or clinical validity
11 standard or otherwise perform as intended by
12 the developer; and

13 “(B) includes an inaccurate false result
14 that reaches a health care provider, patient, or
15 consumer, except that such term excludes any
16 such event or error related to laboratory oper-
17 ations pursuant to section 353 of the Public
18 Health Service Act; and

19 “(3) the term ‘serious injury’ means—

20 “(A) a significant delay in a critical diag-
21 nosis or causing the absence, delay, or dis-
22 continuation of critical medical treatment or
23 that irreversibly or seriously and negatively al-
24 ters the course of the disease or condition; or

25 “(B) an injury that—

1 “(i) is life threatening;

2 “(ii) results in permanent impairment
3 of a body function or permanent damage
4 to a body structure; or

5 “(iii) necessitates medical or surgical
6 intervention to preclude permanent impair-
7 ment of a body function or permanent
8 damage to a body structure.

9 **“SEC. 587M. CORRECTIONS AND REMOVALS.**

10 “(a) IN GENERAL.—The Secretary shall promulgate
11 regulations to implement this section, including informa-
12 tion necessary to be reported to ensure the analytical and
13 clinical validity of in vitro clinical tests, and the safety of
14 specimen receptacles.

15 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—

16 “(1) IN GENERAL.—Each in vitro clinical test
17 developer or importer shall report to the Secretary
18 any correction or removal of an in vitro clinical test
19 undertaken by such developer or importer if the re-
20 moval or correction was undertaken—

21 “(A) to reduce the risk to health posed by
22 the in vitro clinical test; or

23 “(B) to remedy a violation of this Act
24 caused by the in vitro clinical test which may
25 present a risk to health.

1 “(2) EXCEPTION.—No report of the correction
2 or removal of an in vitro clinical test is required
3 under paragraph (1) if a report of the correction or
4 removal is required under, and has been submitted
5 under, section 587L.

6 “(c) TIMING.—A developer or importer shall submit
7 any report required under this subsection to the Secretary
8 within 15 business days of initiating such correction or
9 removal.

10 “(d) RECORDKEEPING.—A developer or importer of
11 an in vitro clinical test who undertakes a correction or re-
12 moval of an in vitro clinical test which is not required to
13 be reported under this subsection shall keep a record of
14 such correction or removal.

15 “(e) RECALL COMMUNICATIONS.—Upon the vol-
16 untary reporting of a correction or removal by the devel-
17 oper—

18 “(1) the Secretary shall classify such correction
19 or removal under this section within 15 calendar
20 days; and

21 “(2) not later than 45 calendar days after the
22 developer or other responsible party notifies the Sec-
23 retary that it has completed a recall action, the Sec-
24 retary shall provide the developer or other respon-
25 sible party with a written statement closing the re-

1 call action or stating the reasons the Secretary can-
2 not close the recall at that time.

3 “(f) LIMITATION.—The developer is not required to
4 report a correction or removal of an in vitro clinical test
5 based solely on an adverse event report under section
6 587L that captures an error within the approved perform-
7 ance standards for such test.

8 “(g) DEFINITIONS.—For purposes of this section—

9 “(1) the term ‘correction’ means the repair,
10 modification, adjustment, relabeling, destruction, or
11 inspection (including patient monitoring) of an in
12 vitro clinical test without its physical removal from
13 its point of use to another location, and does not in-
14 clude routine servicing; and

15 “(2) the term ‘removal’ means the physical re-
16 moval of an in vitro clinical test from its point of use
17 to another location for repair, modification, adjust-
18 ment, relabeling, destruction, or inspection, and does
19 not include routine servicing.

20 **“SEC. 587N. RESTRICTED IN VITRO CLINICAL TESTS.**

21 “(a) APPLICABILITY.—

22 “(1) IN GENERAL.—The Secretary, in issuing
23 an approval of an in vitro clinical test under section
24 587B of a category described in paragraph (3) may
25 require that such test be restricted to sale, distribu-

1 tion, or use upon such conditions as the Secretary
2 may prescribe under paragraph (2).

3 “(2) CONDITIONS PRESCRIBED BY THE SEC-
4 RETARY.—The conditions prescribed by the Sec-
5 retary under this paragraph, with respect to an in
6 vitro clinical test described in paragraph (3), are
7 those conditions which the Secretary determines due
8 to the potentiality for harmful effect of such test (in-
9 cluding any resulting absence, delay, or discontinu-
10 ation of appropriate medical treatment), are nec-
11 essary to assure the analytical or clinical validity of
12 the test, or the safety of a specimen receptacle.

13 “(3) IN VITRO CLINICAL TESTS SUBJECT TO
14 RESTRICTIONS.—The restrictions authorized under
15 this section may be applied by the Secretary to any
16 high-risk in vitro clinical test, prescription home-use
17 in vitro clinical test, direct-to-consumer in vitro clin-
18 ical test, or over-the-counter in vitro clinical test.

19 “(b) LABELING AND ADVERTISING OF A RESTRICTED
20 IN VITRO CLINICAL TEST.—The label, labeling, and ad-
21 vertising of an in vitro clinical test to which restrictions
22 apply under subsection (a) shall bear such appropriate
23 statements of the restrictions as the Secretary may pre-
24 scribe in the approval, provisional approval, technology
25 certification, or regulation, as applicable.

1 “(c) REQUIREMENTS PRIOR TO ENACTMENT.—An in
2 vitro clinical test that was offered, sold, or distributed as
3 a restricted device prior to the enactment date of this sub-
4 chapter shall continue to comply with the applicable re-
5 strictions under section 515 or section 520(e) until the
6 effective date of restrictions issued under subsection (a).

7 **“SEC. 5870. APPEALS.**

8 “(a) SIGNIFICANT DECISION.—

9 “(1) IN GENERAL.—The Secretary shall provide
10 a substantive summary of the scientific and regu-
11 latory rationale for any significant decision of the
12 Center for Devices and Radiological Health regard-
13 ing submission of an application for, or a review of,
14 an in vitro clinical test under section 587B or sec-
15 tion 587D or regarding an exemption under section
16 587A, including documentation of significant con-
17 troversies or differences of opinion and the resolu-
18 tion of such controversies or differences of opinion.

19 “(2) PROVISION OF DOCUMENTATION.—Upon
20 request, the Secretary shall furnish a substantive
21 summary described in paragraph (1) to the person
22 who has made, or is seeking to make, a submission
23 described in such paragraph.

24 “(3) APPLICATION OF LEAST BURDENSOME RE-
25 QUIREMENTS.—The substantive summary required

1 under this subsection shall include a brief statement
2 regarding how the least burdensome requirements
3 were considered and applied consistent with section
4 587B(j), as applicable.

5 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

6 “(1) REQUEST FOR SUPERVISORY REVIEW OF
7 SIGNIFICANT DECISION.—Any person may request a
8 supervisory review of the significant decision de-
9 scribed in subsection (a)(1). Such review may be
10 conducted at the next supervisory level or higher
11 above the agency official who made the significant
12 decision.

13 “(2) SUBMISSION OF REQUEST.—A person re-
14 questing a supervisory review under paragraph (1)
15 shall submit such request to the Secretary not later
16 than 30 days after the decision for which the review
17 is requested and shall indicate in the request wheth-
18 er such person seeks an in-person meeting or a tele-
19 conference review.

20 “(3) TIMEFRAME.—The Secretary shall sched-
21 ule an in-person or teleconference review, if so re-
22 quested, not later than 30 days after such request
23 is made. The Secretary shall issue a decision to the
24 person requesting a review under this subsection not
25 later than 45 days after the request is made under

1 paragraph (1), or, in the case of a person who re-
2 quests an in-person meeting or teleconference, 30
3 days after such meeting or teleconference.

4 “(c) ADVISORY PANELS.—The process established
5 under subsection (a) shall permit the appellant to request
6 review by an advisory committee established under section
7 513 or 587G. The Secretary shall provide a response to
8 an appellant under this subsection not later than 45 days
9 after the requested advisory committee is convened.

10 **“SEC. 587P. ACCREDITED PERSONS.**

11 “(a) IN GENERAL.—

12 “(1) REVIEW OF APPLICATIONS.—

13 “(A) ACCREDITATION FOR APPLICATION
14 REVIEW.—Subject to subparagraph (C), during
15 the period beginning on the date of enactment
16 of the Verifying Accurate Leading-edge IVCT
17 Development Act of 2021 and ending 2 years
18 after the date of enactment of such Act, the
19 Secretary shall accredit persons for any of the
20 following purposes:

21 “(i) Reviewing applications for pre-
22 market approval under section 587B and
23 applications for technology certification
24 under section 587D.

1 “(ii) Making recommendations to the
2 Secretary with respect to an approval of an
3 application under section 587B or issuance
4 of a technology certification order under
5 section 587D.

6 “(B) REQUIREMENT REGARDING REVIEW
7 RECOMMENDATIONS.—

8 “(i) IN GENERAL.—In making a rec-
9 ommendation to the Secretary under this
10 section, an accredited person shall notify
11 the Secretary in writing of the reasons for
12 the recommendation concerning the appli-
13 cation.

14 “(ii) TIME PERIOD FOR REVIEW.—
15 Not later than 30 calendar days after the
16 date on which the Secretary is notified of
17 a recommendation under this section with
18 respect to an application for premarket ap-
19 proval or technology certification, the Sec-
20 retary shall make a determination with re-
21 spect to the application.

22 “(C) LACK OF APPLICATIONS WITHIN 2-
23 YEAR TIMEFRAME.—If the Secretary does not
24 receive applications from persons that meet the

1 criteria under subsection (c) within such period,
2 the Secretary—

3 “(i) may accredit persons under this
4 paragraph after the 2-year period de-
5 scribed in subparagraph (A); and

6 “(ii) shall issue a public notice on the
7 website of the Food and Drug Administra-
8 tion calling for applications for such ac-
9 creditation.

10 “(2) INSPECTIONS.—

11 “(A) ACCREDITATION FOR INSPECTIONS.—

12 Subject to subparagraph (B), during the period
13 beginning on the date of enactment of the
14 Verifying Accurate Leading-edge IVCT Devel-
15 opment Act of 2021 and ending 2 years after
16 the date of enactment of such Act, the Sec-
17 retary shall accredit persons for the purpose of
18 conducting inspections of in vitro clinical test
19 developers and other persons required to reg-
20 ister pursuant to section 587I.

21 “(B) LACK OF APPLICATIONS WITHIN 2-
22 YEAR TIMEFRAME.—If no persons who meet the
23 criteria for such accreditation apply during the
24 2-year period described in subparagraph (A),
25 the Secretary—

1 “(i) may accredit persons under this
2 subparagraph after such period; and

3 “(ii) shall issue a public notice on the
4 website of the Food and Drug Administra-
5 tion calling for applications for such ac-
6 creditation.

7 “(C) EFFECT OF ACCREDITATION.—

8 “(i) IN GENERAL.—Persons accredited
9 under subparagraph (A) to conduct inspec-
10 tions, when conducting such inspections,
11 shall record in writing their specific obser-
12 vations and shall present their observations
13 to the designated representative of the in-
14 spected establishment.

15 “(ii) INSPECTION REPORT REQUIRE-
16 MENTS.—Each person accredited under
17 this paragraph shall prepare and submit to
18 the Secretary an inspection report in a
19 form and manner designated by the Sec-
20 retary for conducting inspections, taking
21 into consideration the goals of inter-
22 national harmonization of quality systems
23 standards. Any official classification of the
24 inspection shall be determined by the Sec-
25 retary. Any statement or representation

1 made by an employee or agent of an estab-
2 lishment to a person accredited to conduct
3 inspections shall be subject to section 1001
4 of title 18, United States Code.

5 “(D) SAVINGS CLAUSE.—Nothing in this
6 section affects the authority of the Secretary to
7 inspect any in vitro clinical test developer or
8 other person registered under section 587I.

9 “(E) INSPECTION LIMITATIONS.—The Sec-
10 retary shall ensure that inspections carried out
11 under this section are not duplicative of inspec-
12 tions carried out under section 353 of the Pub-
13 lic Health Service Act. Inspections under this
14 section shall be limited to the data and informa-
15 tion necessary—

16 “(i) for routine surveillance activities
17 associated with applications under sections
18 587B and 587D; or

19 “(ii) to meet the requirements to re-
20 ceive premarket approval under section
21 587B or a technology certification order
22 under section 587D, as 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
13 180 days after the date of enactment of the
14 Verifying Accurate Leading-edge IVCT Devel-
15 opment Act of 2021, the Secretary shall issue
16 draft guidance on the criteria that the Sec-
17 retary will use to accredit or deny accreditation
18 to a person who requests such accreditation
19 under subsection (a), and not later than one
20 year after the close of the comment period for
21 the draft guidance issued in this section, issue
22 final guidance.

23 “(C) REQUIREMENTS.—

24 “(i) IN GENERAL.—The Secretary
25 shall not accredit or maintain accreditation

1 for a person unless such person meets the
2 minimum qualifications required under
3 subsection (c).

4 “(ii) SCOPE OF ACCREDITATION.—
5 The accreditation of a person under this
6 section shall specify the particular activi-
7 ties under subsection (a) for which such
8 person is accredited.

9 “(D) PUBLIC LIST.—The Secretary shall
10 publish on the website of the Food and Drug
11 Administration a list of persons who are accred-
12 ited under this section. Such list shall be up-
13 dated on at least a monthly basis. The list shall
14 specify the particular activity or activities under
15 this section for which the person is accredited.

16 “(2) ACCREDITATION PROCESS.—

17 “(A) ACCREDITATION PROCESS GUID-
18 ANCE.—The Secretary shall—

19 “(i) not later than 180 days after the
20 date of enactment of the Verifying Accu-
21 rate Leading-edge IVCT Development Act
22 of 2021, issue draft guidance specifying
23 the process for submitting a request for
24 each type of accreditation and reaccredita-
25 tion under this section, including the form

1 and content of information to be submitted
2 in such a request; and

3 “(ii) not later than 1 year after the
4 close of the comment period for the draft
5 guidance, issue final guidance.

6 “(B) RESPONSE TO REQUEST.—The Sec-
7 retary shall respond to a request for accredita-
8 tion or reaccreditation within 60 calendar days
9 of the receipt of the request. The Secretary’s
10 response may be to accredit or reaccredit the
11 person, to deny accreditation, or to request ad-
12 ditional information in support of the request.
13 If the Secretary requests additional informa-
14 tion, the Secretary shall respond within 60 cal-
15 endar days of receipt of such additional infor-
16 mation to accredit or deny the accreditation.

17 “(C) TYPE OF ACCREDITATION.—The ac-
18 creditation or reaccreditation of a person shall
19 specify the particular activity or activities under
20 subsection (a) for which such person is accred-
21 ited, and shall include any limitation to certain
22 eligible in vitro clinical tests.

23 “(D) AUDIT.—The Secretary may audit
24 the performance of persons accredited under
25 this section for purposes of ensuring that such

1 persons continue to meet the published criteria
2 for accreditation, and may modify the scope or
3 particular activities for which a person is ac-
4 credited if the Secretary determines that such
5 person fails to meet one or more criteria for ac-
6 creditation.

7 “(E) SUSPENSION OR WITHDRAWAL.—The
8 Secretary may suspend or withdraw accredita-
9 tion of any person accredited under this section,
10 after providing notice and an opportunity for an
11 informal hearing, when such person is substan-
12 tially not in compliance with the requirements
13 of this section or the published criteria for ac-
14 creditation, or poses a threat to public health,
15 or fails to act in a manner that is consistent
16 with the purposes of this section.

17 “(F) REACCREDITATION.—Accredited per-
18 sons may be initially accredited for up to 4
19 years. After expiration of such initial period,
20 persons may be recredited for unlimited addi-
21 tional 4-year periods, as determined by the Sec-
22 retary.

23 “(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

24 “(1) ELIGIBILITY.—An accredited person, at a
25 minimum, shall—

1 “(A) not be an employee of the Federal
2 Government;

3 “(B) not engage in the activities of a de-
4 veloper, as defined in section 587(7);

5 “(C) not be a person required to register
6 under section 587I, unless such person has es-
7 tablished sufficient processes and protocols to
8 separate activities to develop in vitro clinical
9 tests and the activities for which such person
10 would be accredited under subsection (a) and
11 discloses applicable information under this sec-
12 tion;

13 “(D) not be owned or controlled by, and
14 shall have no organizational, material or finan-
15 cial affiliation with, an in vitro clinical test de-
16 veloper or other person required to register
17 under section 587I;

18 “(E) be a legally constituted entity per-
19 mitted to conduct the activities for which it
20 seeks accreditation;

21 “(F) ensure that the operations of such
22 person are in accordance with generally accept-
23 ed professional and ethical business practices;
24 and

1 “(G) include in its request for accredita-
2 tion a commitment to, at the time of accredita-
3 tion and at any time it is performing activities
4 pursuant to this section—

5 “(i) certify that the information re-
6 ported to the Secretary accurately reflects
7 the data or protocol reviewed, and the doc-
8 umented inspection findings, as applicable;

9 “(ii) limit work to that for which com-
10 petence and capacity are available;

11 “(iii) treat information received or
12 learned, records, reports, and recommenda-
13 tions as proprietary information of the per-
14 son submitting such information; and

15 “(iv) in conducting the activities for
16 which the person is accredited in respect to
17 a particular in vitro clinical test, protect
18 against the use of any employee or consult-
19 ant who has a financial conflict of interest
20 regarding that in vitro clinical test.

21 “(2) WAIVER.—The Secretary may waive any
22 requirements in subparagraph (A), (B), (C), or (D)
23 of paragraph (1) upon making a determination that
24 such person has implemented other appropriate con-

1 trols sufficient to ensure a competent and impartial
2 review.

3 “(d) COMPENSATION OF ACCREDITED PERSONS.—

4 “(1) IN GENERAL.—Compensation of an ac-
5 credited person who reviews an application for pre-
6 market approval submitted under section 587B or
7 an application for technical certification submitted
8 under section 587D shall be determined by agree-
9 ment between the accredited person and the person
10 who engages the services of the accredited person,
11 and shall be paid by the person who engages such
12 services.

13 “(2) INSPECTION ACCREDITATION.—Compensa-
14 tion of an accredited person who is conducting an
15 inspection under section 704 shall be determined by
16 agreement between the accredited person and the
17 person who engages the services of the accredited
18 person, and shall be paid by the person who engages
19 such services.

20 “(e) COOPERATIVE AGREEMENTS.—The Secretary is
21 authorized to enter into cooperative arrangements with of-
22 ficials of foreign countries to ensure that adequate and
23 effective means are available for purposes of determining,
24 from time to time, whether in vitro clinical tests intended
25 for use in the United States by a person whose facility

1 is located outside the United States shall be refused ad-
2 mission on any of the grounds set forth in section 801(a).

3 “(f) INFORMATION SHARING AGREEMENTS.—An ac-
4 credited person may enter into an agreement with a test
5 developer to provide information to the comprehensive test
6 information system under section 587T, including any re-
7 quirements under section 587I.

8 **“SEC. 587Q. RECOGNIZED STANDARDS.**

9 “(a) IN GENERAL.—The Secretary may by order es-
10 tablish performance standards for an in vitro clinical test
11 or tests with the same indication for use to provide reason-
12 able assurance of the analytical validity, clinical validity,
13 or as applicable safety, of that in vitro clinical test or tests
14 with the same indications for use.

15 “(b) OTHER STANDARDS.—The Secretary may recog-
16 nize all or part of appropriate standards established by
17 nationally or internationally recognized standard develop-
18 ment organizations for which a person may submit a dec-
19 laration of conformity in order to meet a requirement
20 under this subchapter to which that standard is applicable.
21 In recognizing a standard, any person requesting recogni-
22 tion of a standard or seeking to use a recognized standard,
23 the Secretary shall follow the processes and requirements,
24 in accordance with section 514(c). Standards for in vitro
25 diagnostic devices previously recognized under section

1 514(c) shall be considered recognized standards under this
2 section. The application of any such consensus standard
3 shall only apply prospectively. The Secretary shall issue
4 guidance establishing the criteria and process for such rec-
5 ognition and adoption.

6 “(c) ORDER PROCESS.—In establishing a standard
7 under subsection (a), the Secretary shall issue a draft
8 order proposing to establish a standard and shall provide
9 for a comment period of not less than 60 calendar days.
10 The Secretary may seek the recommendation of an advi-
11 sory committee under section 587G concerning a proposed
12 standard either prior to or after issuance of a proposed
13 order. After considering the comments and within 90 days
14 of the close of the comment period, the Secretary shall
15 issue a final order adopting the proposed standard, adopt-
16 ing a modification of the proposed standard or terminating
17 the proceeding.

18 “(d) AMENDMENT PROCESS.—The procedures estab-
19 lished in this section or in guidance issued under this sec-
20 tion shall apply to amendment of an existing standard.

21 **“SEC. 587R. INVESTIGATIONAL USE.**

22 “(a) IN GENERAL.—Except as provided in subsection
23 (c), an in vitro clinical test for investigational use shall
24 be exempt from the requirements of this subchapter other
25 than sections 587A, 587O, and 587U.

1 “(b) REGULATIONS.—Not later than 2 years after
2 the date of enactment of the Verifying Accurate Leading-
3 edge IVCT Development Act of 2021, the Secretary shall
4 promulgate regulations to implement this section.

5 “(c) APPLICATION FOR INVESTIGATIONAL USE.—

6 “(1) IN GENERAL.—The following shall apply
7 with respect to in vitro clinical tests for investiga-
8 tional use:

9 “(A) STREAMLINING APPLICATIONS SUB-
10 MITED UNDER THIS SECTION.—Requirements
11 with respect to such tests shall be completed in
12 accordance with current, at the time of submit-
13 ting the application, investigational use require-
14 ments for institutional review boards and cur-
15 rent processes for any analytical or clinical vali-
16 dation.

17 “(B) VARIATION.—The requirements in
18 the regulations promulgated under this section
19 shall take into account variations based on—

20 “(i) the scope and duration of clinical
21 testing to be conducted under investigation
22 that is the subject of such application;

23 “(ii) the number of human subjects
24 that are to be involved in such testing;

1 “(iii) the need to permit changes to be
2 made in the in vitro clinical test involved
3 during testing conducted in accordance
4 with a plan required under paragraph
5 (3)(B); or

6 “(iv) whether the clinical testing of
7 such in vitro clinical test is for the purpose
8 of developing data to obtain approval to
9 offer such test.

10 “(C) SIGNIFICANT RISK STUDIES.—In the
11 case of an in vitro clinical test the investiga-
12 tional use of which poses a significant risk, a
13 sponsor of an investigation of such a test seek-
14 ing an investigational use exemption shall sub-
15 mit to the Secretary an investigational use ap-
16 plication with respect to the test in accordance
17 with paragraphs (2) and (3). For purposes of
18 this subparagraph, the term ‘significant risk’
19 means, with respect to an in vitro clinical test
20 that is a high-risk test, and that the use of the
21 test—

22 “(i) is a use of substantial importance
23 in performing an activity or activities de-
24 scribed in subsection (ss)(1)(A) for, a seri-
25 ous or life-threatening disease or condition

1 without confirmation of the diagnosis by a
2 medically established means;

3 “(ii) requires an invasive sampling
4 procedure that presents a significant risk
5 to the human subject; or

6 “(iii) otherwise presents a reasonably
7 foreseeable serious risk to the health of a
8 human subject.

9 “(D) NON-SIGNIFICANT RISK TESTS.—In
10 the case of an in vitro clinical test, the inves-
11 tigational use of which does not pose a signifi-
12 cant risk—

13 “(i) the sponsor of such investigation
14 shall—

15 “(I) conduct such investigation in
16 compliance with an investigational
17 plan specified in paragraph (5) and
18 labeling specified in paragraph
19 (3)(A)(ii);

20 “(II) ensure each investigator ob-
21 tains informed consent under part 50
22 of title 21, Code of Federal Regula-
23 tions (or any successor regulations),
24 subject to the exceptions set forth in
25 paragraphs (5)(A)(iii) and (5)(B);

1 “(III) submit a listing to the Sec-
2 retary of such investigation; and

3 “(IV) maintain records with re-
4 spect to all requirements in this sub-
5 paragraph; and

6 “(ii) the sponsor may rely on any ex-
7 ception or exemption identified in para-
8 graph (5)(B) or as established by the Sec-
9 retary in regulations issued under sub-
10 section (b).

11 “(2) APPLICATION CONTENT.—An investiga-
12 tional use application shall be submitted in such
13 time and manner and contain such information as
14 the Secretary may require in regulation, and shall
15 include an investigational plan for proposed clinical
16 testing and assurances that the sponsor submitting
17 the application will—

18 “(A) establish and maintain records rel-
19 evant to the investigation of such in vitro clin-
20 ical test; and

21 “(B) submit to the Secretary annual re-
22 ports of data obtained as a result of the inves-
23 tigational use of the in vitro clinical test during
24 the period covered by the exemption that the

1 Secretary reasonably determines will enable the
2 Secretary—

3 “(i) to ensure compliance with the
4 conditions for the exemption specified in
5 paragraph (3);

6 “(ii) to review the progress of the in-
7 vestigation involved; and

8 “(iii) to evaluate the analytical valid-
9 ity and clinical validity of such test.

10 “(3) CONDITIONS FOR EXEMPTION.—

11 “(A) IN GENERAL.—A request for an in-
12 vestigational use exemption with respect to sig-
13 nificant risk tests shall be granted only if each
14 of the following conditions is met:

15 “(i) The risks to the subjects of the in
16 vitro clinical test are outweighed by the an-
17 ticipated benefits to the subjects and the
18 importance of the knowledge to be gained,
19 and adequate assurance of informed con-
20 sent is provided in accordance with para-
21 graph (5)(A)(iii).

22 “(ii) The proposed labeling for the in
23 vitro clinical test involved clearly and con-
24 spicuously states ‘For investigational use’.

1 “(iii) Such other requirements the
2 Secretary determines to be necessary for
3 the protection of the public health and
4 safety as long as the requirements do not
5 unduly delay investigation after finding
6 that the results of such investigation estab-
7 lish sufficient data to support clinical or
8 analytical validity.

9 “(B) CERTAIN SIGNIFICANT RISK IN VITRO
10 CLINICAL TESTS FOR AN UNMET NEED.—As a
11 condition for granting an exemption under this
12 paragraph, the Secretary shall not impose a
13 limit on the sample size for a significant risk in
14 vitro clinical test that meets the requirements
15 of section 587C, as long as such test is devel-
16 oped within a laboratory that is certified to con-
17 duct high-complexity testing under section 353
18 of the Public Health Service Act.

19 “(4) COORDINATION WITH INVESTIGATIONAL
20 NEW DRUG APPLICATIONS.—Any requirement for
21 the submission of a report to the Secretary pursuant
22 to a request for an investigational new drug exemp-
23 tion involving an in vitro clinical test shall supersede
24 the reporting requirement in paragraph (2)(B), but
25 only to the extent the requirement with respect to

1 the request for exemption with respect to the drug
2 is duplicative of the reporting requirement under
3 such paragraph.

4 “(5) INVESTIGATION PLAN REQUIREMENTS.—

5 “(A) IN GENERAL.—With respect to an in-
6 vestigational plan submitted under paragraph
7 (2)(A), the sponsor submitting such plan
8 shall—

9 “(i) in the case of such a plan sub-
10 mitted to an institutional review com-
11 mittee, promptly notify the Secretary of
12 the approval or the suspension or termi-
13 nation of the approval of such plan by an
14 institutional review committee;

15 “(ii) in the case of an in vitro clinical
16 test made available to investigators for
17 clinical testing, assurance that all inves-
18 tigators will comply with this section, regu-
19 lations promulgated or revised under this
20 section, and applicable human subjects reg-
21 ulations; and

22 “(iii) submit an assurance to the Sec-
23 retary that informed consent will be ob-
24 tained from each human subject (or the
25 representative of such subject) of proposed

1 clinical testing involving such in vitro clin-
2 ical test, except in the case that—

3 “(I) there is a life-threatening
4 situation involving the human subject
5 of such testing which necessitates the
6 use of such in vitro clinical test;

7 “(II) it is not feasible to obtain
8 informed consent from the subject;
9 and

10 “(III) there is not sufficient time
11 to obtain such consent from a rep-
12 resentative of such subject.

13 “(B) EXCEPTION.—The informed consent
14 of human subjects shall not be required with re-
15 spect to clinical testing conducted as part of an
16 investigation, if—

17 “(i) the clinical testing uses remnants
18 of specimens collected for routine clinical
19 care or analysis that would have been dis-
20 carded, leftover specimens that were pre-
21 viously collected for other research pur-
22 poses, or specimens obtained from speci-
23 men repositories;

24 “(ii) the identity of the subject of the
25 specimen is not known to, and may not

1 readily be ascertained by, the investigator
2 or any other individual associated with the
3 investigation, including the sponsor;

4 “(iii) any clinical information that ac-
5 companies the specimens does not make
6 the specimen source identifiable to the in-
7 vestigator or any other individual associ-
8 ated with the investigation, including the
9 sponsor;

10 “(iv) the individuals caring for the
11 human subjects as patients are different
12 from, and do not share information about
13 the patient with, the individuals conducting
14 the investigation; and

15 “(v) the specimens are provided to the
16 investigators without personally identifiable
17 information and the supplier of the speci-
18 mens has established policies and proce-
19 dures to prevent the release of personally
20 identifiable information.

21 “(d) REVIEW OF APPLICATIONS.—

22 “(1) IN GENERAL.—The Secretary may issue
23 an order approving an investigation as proposed, ap-
24 proving it with conditions or modifications, or dis-
25 approving it.

1 “(2) FAILURE TO ACT.—Unless the Secretary,
2 not later than the date that is 30 calendar days
3 after the date of the submission of an investigational
4 use exemption request that meets the requirements
5 of subsection (c)(2), issues an order under sub-
6 section (d)(1) and notifies the sponsor submitting
7 the application, the request shall be treated as
8 granted as of such date without further action by
9 the Secretary.

10 “(3) DISAPPROVAL.—The Secretary may deny
11 an investigational use request submitted under this
12 subsection if the Secretary determines that the in-
13 vestigation with respect to which the request is sub-
14 mitted does not conform to the requirements of sub-
15 section (c)(3). A listing of such denial submitted to
16 the sponsor with respect to such a request shall con-
17 tain the order of disapproval and a complete state-
18 ment of the reasons for the Secretary’s denial of the
19 request.

20 “(e) WITHDRAWAL OF APPROVAL.—

21 “(1) IN GENERAL.—The Secretary may, by ad-
22 ministrative order, withdraw an exemption granted
23 under this section with respect to an in vitro clinical
24 test, including an exemption granted based on the
25 Secretary’s failure to act pursuant to subsection

1 (d)(2), if the Secretary determines that the test does
2 not meet the applicable conditions under subsection
3 (c)(3) for such exemption.

4 “(2) OPPORTUNITY TO BE HEARD.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), an order withdrawing the exemption
7 granted under this section may be issued only
8 after the Secretary provides the applicant or
9 sponsor of the test with an opportunity for an
10 informal hearing.

11 “(B) EXCEPTION.—An order referred to in
12 subparagraph (A) with respect to an exemption
13 granted under this subsection may be issued on
14 a preliminary basis before the provision of an
15 opportunity for an informal hearing if the Sec-
16 retary determines that the continuation of test-
17 ing under the exemption will result in an unrea-
18 sonable risk to the public health. The Secretary
19 will provide an opportunity for an informal
20 hearing promptly following any preliminary ac-
21 tion under this subparagraph.

22 “(f) CHANGES.—

23 “(1) IN GENERAL.—The regulations promul-
24 gated under subsection (b) shall provide, with re-
25 spect to an in vitro clinical test for which an exemp-

1 tion under this subsection is in effect, procedures
2 and conditions under which the changes to the test
3 are allowed without the additional determination on
4 a request for an exemption or submission of a sup-
5 plement to such a request. Such regulations shall
6 provide that such a change may be made if—

7 “(A) the sponsor or applicant determines,
8 on the basis of credible information (as defined
9 by the Secretary) that the change meets the
10 conditions specified in paragraph (2); and

11 “(B) the sponsor or applicant submits to
12 the Secretary, not later than 5 calendar days
13 after making the change, a notice of the
14 change.

15 “(2) CONDITIONS.—The conditions specified in
16 this paragraph are that—

17 “(A) in the case of developmental changes
18 to an in vitro clinical test (including manufac-
19 turing changes), the changes—

20 “(i) do not constitute a significant
21 change in design or in basic principles of
22 operation;

23 “(ii) do not affect the rights, safety,
24 or welfare of the human subjects (if any)
25 involved in the investigation; and

1 “(iii) are made in response to infor-
2 mation gathered during the course of an
3 investigation; and

4 “(B) in the case of changes to clinical pro-
5 tocols applicable to the test, the changes do not
6 affect—

7 “(i) the validity of data or information
8 resulting from the completion of an ap-
9 proved clinical protocol;

10 “(ii) the scientific soundness of a plan
11 submitted under subsection (c)(5); or

12 “(iii) the rights, safety, or welfare of
13 the human subjects (if any) involved in the
14 investigation.

15 “(g) CLINICAL HOLD.—

16 “(1) IN GENERAL.—At any time, the Secretary
17 may impose a clinical hold with respect to an inves-
18 tigation of an in vitro clinical test if the Secretary
19 makes a determination described in paragraph (2).
20 The Secretary shall, in imposing such clinical hold,
21 specify the basis for the clinical hold, including the
22 specific information available to the Secretary which
23 served as the basis for such clinical hold, and con-
24 firm such determination in writing. The applicant or

1 sponsor may immediately appeal any such deter-
2 mination pursuant to section 587O.

3 “(2) DETERMINATION.—For purposes of para-
4 graph (1), a determination described in this sub-
5 paragraph with respect to a clinical hold is a deter-
6 mination that—

7 “(A) the in vitro clinical test involved rep-
8 resents an unreasonable risk to the safety of
9 the persons who are the subjects of the clinical
10 investigation, taking into account the qualifica-
11 tions of the clinical investigators, information
12 about the in vitro clinical test, the design of the
13 clinical investigation, the condition for which
14 the in vitro clinical test is to be investigated,
15 and the health status of the subjects involved;

16 “(B) the clinical hold should be issued for
17 such other reasons as the Secretary may by
18 regulation establish; or

19 “(C) any written request to the Secretary
20 from the sponsor of an investigation that a clin-
21 ical hold be removed shall receive a decision, in
22 writing and specifying the reasons therefor,
23 within 30 days after receipt of such request.
24 Any such request shall include sufficient infor-

1 mation to support the removal of such clinical
2 hold.

3 **“SEC. 587S. COLLABORATIVE COMMUNITIES FOR IN VITRO**
4 **CLINICAL TESTS.**

5 “(a) IN GENERAL.—

6 “(1) For the purposes of facilitating community
7 solutions and decision making with respect to in
8 vitro clinical tests, the Secretary may participate in
9 collaborative communities comprised of public and
10 private participants that may provide recommenda-
11 tions and other advice to the Secretary on the devel-
12 opment and regulation of in vitro clinical tests.

13 “(2) A collaborative community under this sec-
14 tion shall have broad representation of interested
15 private and public-sector stakeholder communities
16 and may include patients, care partners, academics,
17 health care professionals, health care systems,
18 payors, Federal and State agencies, entities respon-
19 sible for accrediting clinical laboratories, inter-
20 national regulatory bodies, test developers, or other
21 interested entities or communities.

22 “(b) GUIDANCE.—The Secretary shall issue a draft
23 guidance not later than 180 days after the date of enact-
24 ment of the Verifying Accurate Leading-edge IVCT Devel-
25 opment Act of 2021, addressing the participation process

1 and framework to build consensus, and how the Secretary
2 may consider, review, and implement recommendations
3 under subsection (c).

4 “(c) RECOMMENDATIONS.—A collaborative commu-
5 nity for in vitro clinical tests may make recommendations
6 to the Secretary on matters including—

7 “(1) mitigating measures for in vitro clinical
8 tests;

9 “(2) standards development activities and per-
10 formance standards for in vitro clinical tests or
11 groups of such tests;

12 “(3) scientific and clinical evidence to support
13 new claims for in vitro clinical tests;

14 “(4) new technologies and methodologies re-
15 lated to in vitro clinical tests;

16 “(5) stakeholder communication and engage-
17 ment; and

18 “(6) development of effective policies and proc-
19 esses, including to develop tests, and to regulate
20 such tests in accordance with least burdensome re-
21 quirements described in section 587B(j).

22 “(d) USE BY SECRETARY.—

23 “(1) IN GENERAL.—The Secretary may adopt
24 recommendations made under subsection (b), or oth-
25 erwise incorporate the feedback from collaborative

1 communities into regulatory decision making,
2 through rulemaking or guidance, as appropriate.

3 “(2) CLARIFICATION.—The Secretary is not re-
4 quired to adopt recommendations submitted by col-
5 laborative communities.

6 “(e) TRANSPARENCY.—The Secretary shall—

7 “(1) publish on the website of the Food and
8 Drug Administration matters for which it is seeking
9 comments or recommendations, in a timely manner;

10 “(2) maintain a list of all collaborative commu-
11 nities in which the Secretary participates and make
12 such list available on the website of the Food and
13 Drug Administration; and

14 “(3) post on the website of the Food and Drug
15 Administration at least once every year a report on
16 the recommendations it has adopted and rec-
17 ommendations it has not adopted from collaborative
18 communities.

19 “(f) PARTICIPATION.—The Secretary may participate
20 in a collaborative community only if such community re-
21 quires members to disclose conflicts of interest and has
22 established a process to address conflicts of interest.

23 “(g) EXEMPTION.—The collaborative communities
24 established and used in accordance with this section shall

1 be exempt from the Federal Advisory Committee Act (5
2 U.S.C. App.).

3 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

4 “(a) PURPOSE.—For the purposes of improving the
5 transparency of information on in vitro clinical tests and
6 allowing patients and health care providers better access
7 to information about in vitro clinical tests, the Secretary
8 shall establish a comprehensive test information system.

9 “(b) ESTABLISHMENT.—Not later than 2 years after
10 the date of enactment of the Verifying Accurate Leading-
11 edge IVCT Development Act of 2021, the Secretary shall
12 make available a comprehensive test information system
13 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, to access the—

18 “(A) regulatory pathway designation infor-
19 mation for each in vitro clinical test or tests
20 with the same indications for use;

21 “(B) registration and listing information
22 provided by developers under section 587I, in-
23 cluding the use of a link for labels;

24 “(C) adverse event reports submitted
25 under section 587L;

1 “(D) reports of corrections and removals
2 submitted under section 587M; 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.

11 “(c) SUBMISSION FUNCTION.—The comprehensive
12 test information system shall serve as the electronic sub-
13 mission service for test developers submitting information
14 for applications under sections 587B and 587D.

15 **“SEC. 587U. PREEMPTION.**

16 “(a) IN GENERAL.—No State, Tribal, or local gov-
17 ernment (or political subdivision thereof) may establish or
18 continue in effect any requirement related to the develop-
19 ment, manufacture, labeling, distribution, sale, or use of
20 an in vitro clinical test that is different from, or in addi-
21 tion to, the requirements of this subchapter.

22 “(b) EXCEPTIONS.—Subsection (a) shall not be con-
23 strued to affect the authority of a State, Tribal, or local
24 government—

1 “(1) to license laboratory personnel, health care
2 practitioners, or health care facilities or to regulate
3 any aspect of a health care practitioner-patient rela-
4 tionship; or

5 “(2) to enforce laws of general applicability,
6 such as zoning laws, environmental laws, labor laws,
7 and general business laws.

8 “(c) CLARIFICATION.—This section shall not be con-
9 strued to shift liability to health care practitioners or other
10 users.

11 **“SEC. 587V. ADULTERATION.**

12 “An in vitro clinical test shall be deemed to be adul-
13 terated:

14 “(1) If it consists in whole or in part of any
15 filthy, putrid, or decomposed substance.

16 “(2) If it has been developed, prepared, packed,
17 or held under insanitary conditions whereby it may
18 have been contaminated with filth, or whereby it
19 may have been rendered injurious to health.

20 “(3) If its container or package is composed, in
21 whole or in part, of any poisonous or deleterious
22 substance which may render the contents injurious
23 to health.

1 “(4) If it bears or contains, for purposes of
2 coloring only, a color additive which is unsafe within
3 the meaning of section 721(a).

4 “(5) If its analytical or clinical validity, or with
5 respect to a specimen receptacle, its safety, or its
6 strength, purity, or quality, differs from or falls
7 below that which it purports or is represented to
8 possess.

9 “(6) If it is required to be, declared to be, pur-
10 ports to be, or is represented as being, in conformity
11 with any performance standard established or recog-
12 nized under section 587Q and is not in all respects
13 in conformity with such standard.

14 “(7) If it is required to be in conformity with
15 a mitigating measure established under section
16 587E and is not in all respects in conformity with
17 such mitigating measure.

18 “(8) If it fails to have an approved premarket
19 application under section 587B unless such in vitro
20 clinical test can be lawfully offered—

21 “(A) for clinical use pursuant to an exemp-
22 tion under section 587A;

23 “(B) for emergency use pursuant to an au-
24 thorization under section 564; or

1 “(C) for investigational use pursuant to
2 section 587R.

3 “(9) If it is not in conformity with any condi-
4 tion established under section 587B, 587D, or 564.

5 “(10) If it purports to be an in vitro clinical
6 test that is offered for clinical use subject to an ex-
7 emption under section 587A and it fails to meet or
8 maintain any criteria, condition, or requirement of
9 such exemption.

10 “(11) If it has been granted an exemption
11 under section 587R for investigational use, and the
12 person granted such exemption or any investigator
13 who uses such in vitro clinical test under such ex-
14 emption fails to comply with a requirement pre-
15 scribed by or under such section.

16 “(12) If it fails to meet the quality require-
17 ments prescribed in or established under section
18 587J (as applicable), or the methods used in, or fa-
19 cilities or controls used for, its development, manu-
20 facture, packing, storage, or installation are not in
21 conformity with applicable requirements established
22 under such section.

23 “(13) If it has been developed, manufactured,
24 processed, packed or held in any establishment, fac-
25 tory, or warehouse and the owner, operator or agent

1 of such establishment, factory, or warehouse delays,
2 denies, or limits an inspection, or refuses to permit
3 entry or inspection.

4 “(14) If it is not in compliance with any restric-
5 tion required under section 587N.

6 **“SEC. 587W. MISBRANDING.**

7 “An in vitro clinical test shall be deemed to be mis-
8 branded:

9 “(1) If its labeling is false or misleading in any
10 particular.

11 “(2) If in a package form unless it bears a label
12 containing—

13 “(A) the name and place of business of the
14 test developer, manufacturer, packer, or dis-
15 tributor; and

16 “(B) an accurate statement of the quantity
17 of contents in terms of weight, measure, or nu-
18 merical count with respect to small packages,
19 unless an exemption is granted by the Secretary
20 by the issuance of guidance.

21 “(3) If any word, statement, or other informa-
22 tion required by or under authority of this Act to
23 appear on the label or labeling, including a test re-
24 port, is not prominently placed thereon with such
25 conspicuousness (as compared with other words,

1 statements, designs, or devices, in the labeling) and
2 in such terms as to render it likely to be read and
3 understood by the ordinary individual under cus-
4 tomary conditions of purchase and use.

5 “(4) Unless its labeling bears adequate direc-
6 tions for use and such adequate warnings as are
7 necessary for the protection of users of the in vitro
8 clinical test and recipients of the results of such in
9 vitro clinical test, including patients, consumers, do-
10 nors, and related health care professionals. Required
11 labeling for in vitro clinical tests intended for use in
12 health care facilities or by a health care professional
13 may be made available solely by electronic means,
14 provided that the labeling complies with all applica-
15 ble requirements of law, and that the test developer,
16 manufacturer, or distributor affords such users the
17 opportunity to request the labeling in paper form,
18 and after such request, promptly provides the re-
19 quested information without additional cost.

20 “(5) If it causes serious or adverse health con-
21 sequences or death, including through absence,
22 delay, or discontinuation in diagnosis or treatment,
23 when used in the manner prescribed, recommended,
24 or suggested in the labeling thereof.

1 “(6) If it was developed or manufactured in an
2 establishment not duly registered under section 587I
3 or it was not included in a listing under section
4 587I, in accordance with timely reporting require-
5 ments under this subchapter.

6 “(7) In the case of any in vitro clinical test sub-
7 ject to restrictions under section 587N, (1) if its ad-
8 vertising is false or misleading in any particular, (2)
9 if it is offered for clinical use, sold, distributed, or
10 used in violation of such restrictions, or (3) unless
11 the test developer, manufacturer, or distributor in-
12 cludes in all advertisements and other descriptive
13 printed matter that such person issues or causes to
14 be issued, a brief statement of the intended uses of
15 the in vitro clinical test and relevant warnings, pre-
16 cautions, side effects, and contraindications. This
17 subsection shall not be applicable to any printed
18 matter that the Secretary determines to be labeling
19 as defined in section 201(m) or section 587K.

20 “(8) If it was subject to a mitigating measure
21 established under section 587E, unless it bears such
22 labeling as may be prescribed in such mitigating
23 measure.

1 “(9) If it was subject to a standard established
2 under section 587Q, unless it bears such labeling as
3 may be prescribed in such standard.

4 “(10) Unless it bears such labeling as may be
5 prescribed by or established under an applicable la-
6 beling requirement under this Act.

7 “(11) If there was a failure or refusal to comply
8 with any requirement prescribed under section 587I
9 or 587X, or to comply with a requirement under sec-
10 tion 587Y, or to provide any report, material, or in-
11 formation required under this subchapter.

12 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

13 “(a) IN GENERAL.—

14 “(1) IN GENERAL.—In addition to other appli-
15 cable requirements under this Act, the Secretary
16 may issue an order requiring a developer to conduct
17 postmarket surveillance of a single in vitro clinical
18 test as a condition of approval under section 587B.

19 “(2) EXEMPT TESTS.—The Secretary may
20 order postmarket surveillance for tests exempt pur-
21 suant to section 587A for which the failure of the
22 in vitro clinical test to meet the applicable standard
23 for approval is likely to result in serious or adverse
24 health consequences or death from use of the single
25 in vitro clinical test.

1 “(3) CONSIDERATION.—In determining whether
2 to require a developer to conduct postmarket surveil-
3 lance of an in vitro clinical test, the Secretary shall
4 take into consideration the benefits and risks for the
5 patient and the least burdensome principles under
6 section 587B.

7 “(b) SURVEILLANCE APPROVAL.—

8 “(1) Each developer required to conduct a sur-
9 veillance of an in vitro clinical test shall submit,
10 within 30 days of receiving an order from the Sec-
11 retary, a plan for the required surveillance. The Sec-
12 retary, within 60 days of the receipt of such plan,
13 shall determine if the person designated to conduct
14 the surveillance has the appropriate qualifications
15 and experience to undertake such surveillance and if
16 the plan will result in useful data that can reveal un-
17 foreseen adverse events or other information nec-
18 essary to protect the health of patients or the public.

19 “(2) The developer shall commence surveillance
20 under this section not later than 15 months after
21 the day on which the Secretary orders such postmar-
22 ket surveillance, unless the Secretary determines
23 more time is needed to commence surveillance.

24 “(3) The Secretary may order a prospective
25 surveillance period of up to 3 years. Any determina-

1 tion by the Secretary that a longer period is nec-
2 essary shall be made by mutual agreement between
3 the Secretary and the manufacturer or, if no agree-
4 ment can be reached, after the completion of a dis-
5 pute resolution process.

6 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

7 “(a) IN GENERAL.—All presubmissions and submis-
8 sions to the Food and Drug Administration with respect
9 to an in vitro clinical test shall include an electronic copy
10 of such presubmission or submission, and, with respect to
11 the information required under sections 587B and 587D,
12 shall utilize the system described in section 587T.

13 “(b) ELECTRONIC FORMAT.—Beginning on such date
14 as the Secretary specifies in final guidance issued under
15 subsection (c), presubmissions and submissions for in vitro
16 clinical tests (and any appeals of action taken by the Sec-
17 retary with respect to such presubmissions and submis-
18 sions) shall be submitted solely in such electronic format
19 as specified by the Secretary in such guidance.

20 “(c) GUIDANCE.—The Secretary shall issue guidance
21 implementing this section. In such guidance, the Secretary
22 may—

23 “(1) provide standards for the electronic copy
24 required under subsection (a) or the submission in
25 electronic format required under subsection (b);

1 “(2) set forth criteria for waivers of or exemp-
2 tions from the requirements of subsection (a) or (b);
3 and

4 “(3) provide any other information for the effi-
5 cient implementation and enforcement of this sec-
6 tion.

7 **“SEC. 587Z. POSTMARKET REMEDIES.**

8 “(a) SAFETY NOTICE.—

9 “(1) IN GENERAL.—If the Secretary determines
10 that an in vitro clinical test presents an unreason-
11 able risk of substantial harm to the public health,
12 and notification under this subsection is necessary to
13 eliminate the unreasonable risk of such harm and no
14 more practicable means is available under the provi-
15 sions of this Act (other than this section) to elimi-
16 nate the risk, the Secretary may issue such order as
17 may be necessary to ensure that adequate safety no-
18 tice is provided in an appropriate form, by the per-
19 sons and means best suited under the circumstances,
20 to all health care professionals who prescribe, order,
21 or use the in vitro clinical test and to any other per-
22 son (including developers, manufacturers, importers,
23 distributors, retailers, and users) who should prop-
24 erly receive such 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 advise 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 or
9 manufacture;

10 “(iii) there are reasonable grounds to
11 believe that the unreasonable risk was not
12 caused by failure of a person other than a
13 developer, manufacturer, importer, dis-
14 tributor, or retailer of the in vitro clinical
15 test to exercise due care in the installation,
16 maintenance, repair, or use of the in vitro
17 clinical test; and

18 “(iv) the notice authorized by sub-
19 section (a) would not by itself be sufficient
20 to eliminate the unreasonable risk and ac-
21 tion described in paragraph (2) of this sub-
22 section is necessary to eliminate such risk,
23 the Secretary may order the developer, manu-
24 facturer, importer, or any distributor of such in
25 vitro clinical test, or any combination of such

1 persons, to submit to him within a reasonable
2 time a plan for taking one or more of the ac-
3 tions described in paragraph (2). An order
4 issued under the preceding sentence which is di-
5 rected to more than one person shall specify
6 which person may decide which action shall be
7 taken under such plan and the person specified
8 shall be the person who the Secretary deter-
9 mines bears the principal, ultimate financial re-
10 sponsibility for action taken under the plan un-
11 less the Secretary cannot determine who bears
12 such responsibility or the Secretary determines
13 that the protection of the public health requires
14 that such decision be made by a person (includ-
15 ing a health professional or user of the in vitro
16 clinical test) other than the person the Sec-
17 retary determines bears such responsibility.

18 “(B) SECRETARY APPROVAL OF PLAN.—
19 Within 30 calendar days of issuing an order
20 under subparagraph (A), the Secretary shall ap-
21 prove a plan submitted pursuant to an order
22 issued under subparagraph (A) unless the Sec-
23 retary determines (after affording opportunity
24 for an informal hearing) that the action or ac-
25 tions to be taken under the plan or the manner

1 in which such action or actions are to be taken
2 under the plan will not assure that the unrea-
3 sonable risk with respect to which such order
4 was issued will be eliminated. If the Secretary
5 disapproves a plan, the Secretary shall order a
6 revised plan to be submitted within a reason-
7 able time. If the Secretary determines (after af-
8 fording opportunity for an informal hearing)
9 that the revised plan is unsatisfactory or if no
10 revised plan or no initial plan has been sub-
11 mitted to the Secretary within the prescribed
12 time, the Secretary shall (i) prescribe a plan to
13 be carried out by the person or persons to
14 whom the order issued under subparagraph (A)
15 was directed, or (ii) after affording an oppor-
16 tunity for an informal hearing, by order pre-
17 scribe a plan to be carried out by a person who
18 is a manufacturer, importer, distributor, or re-
19 tailer of the in vitro clinical test with respect to
20 which the order was issued but to whom the
21 order under subparagraph (A) was not directed.

22 “(2) ACTIONS ON A PLAN.—The actions which
23 may be taken under a plan submitted under an
24 order issued under paragraph (1) are as follows:

1 “(A) To repair the in vitro clinical test so
2 that it does not present the unreasonable risk
3 of substantial harm with respect to which the
4 order under paragraph (1)(A) was issued.

5 “(B) To replace the in vitro clinical test
6 with a like or equivalent test which is in con-
7 formity with all applicable requirements of this
8 Act.

9 “(C) To refund the purchase price of the
10 in vitro clinical test (less a reasonable allowance
11 for use if such in vitro clinical test has been in
12 the possession of the user for one year or more
13 at the time of notice ordered under subsection
14 (a), or at the time the user receives actual no-
15 tice of the unreasonable risk with respect to
16 which the order was issued under paragraph
17 (1)(A), whichever occurs first).

18 “(3) NO CHARGE.—No charge shall be made to
19 any person (other than a developer, manufacturer,
20 importer, distributor or retailer) for using a remedy
21 described in paragraph (2) and provided under an
22 order issued under paragraph (1), and the person
23 subject to the order shall reimburse each person
24 (other than a developer, manufacturer, importer,
25 distributor, or retailer) who is entitled to such a

1 remedy for any reasonable and foreseeable expenses
2 actually incurred by such person in availing himself
3 of such remedy.

4 “(c) REIMBURSEMENT.—An order issued under sub-
5 section (b)(1)(A) with respect to an in vitro clinical test
6 may require any person who is a developer, manufacturer,
7 importer, distributor, or retailer of the in vitro clinical test
8 to reimburse any other person who is a developer, manu-
9 facturer, importer, distributor, or retailer of such in vitro
10 clinical test for such other person’s expenses actually in-
11 curred in connection with carrying out the order if the
12 Secretary determines such reimbursement is required for
13 the protection of the public health. Any such requirement
14 shall not affect any rights or obligations under any con-
15 tract to which the person receiving reimbursement or the
16 person making such reimbursement is a party.

17 “(d) RECALL AUTHORITY.—

18 “(1) IN GENERAL.—If the Secretary finds that
19 there is a reasonable probability that an in vitro
20 clinical test approved under section 587B would
21 cause serious, adverse health consequences or death,
22 including by the absence, delay, or discontinuation of
23 appropriate medical treatment, the Secretary shall
24 issue an order requiring the appropriate person (in-
25 cluding the developers, manufacturers, importers,

1 distributors, or retailers of the in vitro clinical
2 test)—

3 “(A) to immediately cease distribution of
4 such in vitro clinical test; and

5 “(B) to immediately notify health profes-
6 sionals and user facilities of the order and to
7 instruct such professionals and facilities to
8 cease use of such in vitro clinical test.

9 “(2) INFORMAL HEARING.—The order issued
10 under paragraph (1)(A), shall provide the person
11 subject to the order with an opportunity for an in-
12 formal hearing, to be held not later than 10 calendar
13 days after the date of the issuance of the order, on
14 the actions required by the order and on whether the
15 order should be amended to require a recall of such
16 in vitro clinical test. If, after providing an oppor-
17 tunity for such a hearing, the Secretary determines
18 that inadequate grounds exist to support the actions
19 required by the order, the Secretary shall vacate the
20 order.

21 “(3) AMENDED ORDER.—

22 “(A) IN GENERAL.—If, after providing an
23 opportunity for an informal hearing under
24 paragraph (2), the Secretary determines that
25 the order should be amended to include a recall

1 of the in vitro clinical test with respect to which
2 the order was issued, the Secretary shall, except
3 as provided in subparagraph (B), amend the
4 order to require a recall. The Secretary shall
5 specify a timetable in which the recall will occur
6 and shall require periodic reports describing the
7 progress of the recall.

8 “(B) REQUIREMENTS.—An amended order
9 under subparagraph (A)—

10 “(i) shall not include recall of the in
11 vitro clinical test from individuals;

12 “(ii) shall not include recall of an in
13 vitro clinical test from test user facilities if
14 the Secretary determines that the risk of
15 recalling such in vitro clinical test from the
16 facilities presents a greater health risk
17 than the health risk of not recalling the in
18 vitro clinical test from use; and

19 “(iii) shall provide for notice to indi-
20 viduals subject to the risks associated with
21 the use of such in vitro clinical test. In
22 providing the notice required by this
23 clause, the Secretary may use the assist-
24 ance of health professionals who pre-

1 scribed, ordered, or used such an in vitro
2 clinical test for individuals.

3 “(4) CLARIFICATION.—The remedy provided by
4 this subsection shall be in addition to remedies pro-
5 vided by subsections (b) and (c).”.

6 **SEC. 4. ENFORCEMENT AND OTHER PROVISIONS.**

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

10 (1) in paragraphs (a), (b), (c), (g), (k), (q), (r),
11 and (y), by inserting “in vitro clinical test,” after
12 “device,” each place it appears;

13 (2) in paragraph (y) by inserting “or 587P”
14 after “section 523” each place it appears; and

15 (3) by adding at the end, the following:

16 “(fff)(1) The introduction or delivery for introduction
17 into interstate commerce of an in vitro clinical test in vio-
18 lation of section 587B(a).

19 “(2) The false, fraudulent, or deceptive claiming for
20 an in vitro clinical test of an exemption from the pre-
21 market review required under section 587B.

22 “(3) When claiming an exemption under section
23 587A from the premarket review required under section
24 587B, the failure to maintain complete and accurate docu-
25 mentation for the exemption as required under section

1 587A or the failure to provide labeling required under sec-
2 tion 587A.

3 “(4) With respect to an in vitro clinical test, the sub-
4 mission of any report that is required by or under this
5 Act that is false or misleading in any material respect.

6 “(5) The making of a false, fraudulent, or materially
7 deceptive analytical or clinical claim for an in vitro clinical
8 test—

9 “(A) in any application, report, or notification
10 submitted to the Secretary under this Act; or

11 “(B) in the labeling or advertising of an in vitro
12 clinical test.

13 “(6) The failure to comply with a condition of ap-
14 proval, performance standard, mitigating measure, or re-
15 striction established in an order approving an application
16 or supplement under section 587B; the failure to perform
17 a risk analysis required by section 587B; the failure to
18 submit an annual report required under section 587B(k);
19 or the failure to complete postmarket studies required
20 under section 587V.

21 “(7) The marketing of an in vitro clinical test in vio-
22 lation of—

23 “(A) an order issued by the Secretary under
24 section 587A; or

25 “(B) any requirement under section 587A.

1 “(8) With respect to technology certification under
2 section 587D, the refusal to permit, or unreasonable delay
3 in permitting, an inspection authorized under section
4 587D(f)(3)(G); the failure to comply with applicable re-
5 quirements to submit an application or report under sec-
6 tion 587D(e); or the failure to comply with applicable
7 maintenance requirements under section 587D(h).

8 “(9) The failure to comply with an applicable miti-
9 gating measure established under section 587E or to
10 maintain the documentation required under section
11 587E(b); or the failure to comply with a performance
12 standard established under section 587Q.

13 “(10) The failure to register in accordance with sec-
14 tion 587I, the failure to provide information required
15 under section 587I(b), or the failure to maintain or submit
16 information required under section 587I(c).

17 “(11) The failure to submit a report required under
18 section 587L or 587M; the failure to comply with a re-
19 striction imposed under section 587N; or the failure to
20 comply with labeling and advertising requirements under
21 section 587N(b).

22 “(12) The failure to comply with the requirements
23 of section 587P (relating to accredited persons).

24 “(13) The failure to comply with any requirement
25 prescribed or established under section 587R; the failure

1 to furnish any notification, information, material, or re-
2 port required under section 587R; or the failure to comply
3 with an order issued under section 587R.”.

4 (b) PENALTIES.—Section 303(f)(1) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)) is
6 amended—

7 (1) in subparagraph (A), by inserting “or in
8 vitro clinical tests” after “devices”; and

9 (2) in subparagraph (B)(i)—

10 (A) by inserting “, or 587J or 587L,”
11 after “520(f)”; and

12 (B) by inserting “, or who violates section
13 587M(b) with respect to a correction report”
14 after “risk to public health”.

15 (c) SEIZURE.—Section 304 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

17 (1) in subsection (a)(2)—

18 (A) by striking “and” before “(E) Any”;

19 and

20 (B) by inserting “, and (F) Any adulter-
21 ated or misbranded in vitro clinical test” after
22 “tobacco product”;

23 (2) in subsection (d)(1), by inserting “in vitro
24 clinical test,” after “device,”; and

25 (3) in subsection (g)—

1 (A) in paragraph (1), by inserting “, in
2 vitro clinical test,” after “device” each place it
3 appears; and

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by inserting
6 “, in vitro clinical test,” after “device”;
7 and

8 (ii) in subparagraph (B), by inserting
9 “or in vitro clinical test” after “device”
10 each place it appears.

11 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
12 PROVAL, AND SUSPENSION.—Section 306 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
14 amended by adding at the end the following:

15 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
16 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
17 REVIEWS.—

18 “(1) IN GENERAL.—If the Secretary finds that
19 a person has been convicted of a felony under sec-
20 tion 301(gg), 301(fff)(2), 301(fff)(5), or 301(fff)(8),
21 the Secretary shall debar such person from being ac-
22 credited under section 587P and from carrying out
23 activities under an agreement described in section
24 803(b).

1 “(2) DEBARMENT PERIOD.—The Secretary
2 shall debar a person under paragraph (1) for the fol-
3 lowing periods:

4 “(A) The period of debarment of a person
5 (other than an individual) shall not be less than
6 1 year or more than 10 years, but if an act
7 leading to a subsequent debarment under such
8 paragraph occurs within 10 years after such
9 person has been debarred under such para-
10 graph, the period of debarment shall be perma-
11 nent.

12 “(B) The debarment of an individual shall
13 be permanent.

14 “(3) TERMINATION OF DEBARMENT; JUDICIAL
15 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
16 (e), (i), (j), and (l)(1) apply with respect to a person
17 (other than an individual) or an individual who is
18 debarred under paragraph (1) to the same extent
19 and in the same manner as such subsections apply
20 with respect to a person who is debarred under sub-
21 section (a)(1), or an individual who is debarred
22 under subsection (a)(2), respectively.”.

23 (e) JUDICIAL REVIEW.—Section 517(a) of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a))
25 is amended—

1 (1) in paragraph (8), by striking “or” at the
2 end;

3 (2) in paragraph (9), by inserting “or” after
4 the comma at the end; and

5 (3) before the matter that follows paragraph
6 (9), by inserting the following:

7 “(10) an order issued pursuant to section
8 587B, 587D, 587R, or 587S.”.

9 (f) EXPANDED ACCESS TO UNAPPROVED THERAPIES
10 AND DIAGNOSTICS.—Section 561 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
12 ed—

13 (1) in subsections (a) through (d)—

14 (A) by striking “or investigational devices”
15 each place it appears and inserting “, investiga-
16 tional devices, or investigational in vitro clinical
17 tests”; and

18 (B) by striking “or investigational device”
19 each place it appears (other than the second
20 such place in paragraph (3)(A)) and inserting
21 “, investigational device, or investigational in
22 vitro clinical test”;

23 (2) in subsection (b)(4) by striking “or 520(g)”
24 and inserting “, 520(g), or 587R” each place it ap-
25 pears;

1 (3) in subsection (c)—

2 (A) by amending the subsection heading to
3 read: “TREATMENT INVESTIGATIONAL NEW
4 DRUG APPLICATIONS, TREATMENT INVESTIGA-
5 TIONAL DEVICE EXEMPTIONS, AND TREAT-
6 MENT INVESTIGATIONAL IN VITRO CLINICAL
7 TEST EXEMPTIONS”;

8 (B) in paragraph (3)(A), by striking “or
9 investigational device exemption in effect under
10 section 520(g)” and inserting “, investigational
11 device exemption in effect under section 520(g),
12 or investigational in vitro clinical test exemption
13 under section 587R”;

14 (C) by striking “or treatment investiga-
15 tional device exemption” each place it appears
16 and inserting “, treatment investigational device
17 exemption, or treatment investigational in vitro
18 clinical test exemption”; and

19 (D) in the matter following paragraph (7)
20 by striking “or 520(g)” each place it appears
21 and inserting “, 520(g) or 587R”; and

22 (4) by amending subsection (e) to read as fol-
23 lows:

24 “(e) DEFINITIONS.—In this section, the terms ‘inves-
25 tigational drug’, ‘investigational device’, ‘investigational in

1 vitro clinical test’, ‘treatment investigational new drug ap-
2 plication’, ‘treatment investigational device exemption’,
3 and ‘treatment investigational in vitro clinical test exemp-
4 tion’ shall have the meanings given the terms in regula-
5 tions prescribed by the Secretary.”.

6 (g) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
7 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 360bbb–8a(b)) is amended by inserting “an in
9 vitro clinical test, as defined in subsection (ss) of such sec-
10 tion,” before “or a biological product”.

11 (h) PATIENT PARTICIPATION IN MEDICAL PRODUCT
12 DISCUSSION.—The heading of subsection (a) of section
13 569C of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 360bbb–8c) is amended by striking “DRUGS AND
15 DEVICES” and inserting “DRUGS, DEVICES, AND IN
16 VITRO CLINICAL TESTS”.

17 (i) REGULATIONS AND HEARINGS.—Section
18 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting
20 “and in vitro clinical tests” after “devices”.

21 (j) FACTORY INSPECTION.—Section 704 of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
23 than subsection (g)) is amended—

1 (1) by striking “drugs or devices” each place it
2 appears and inserting “drugs, devices, or in vitro
3 clinical tests”;

4 (2) in subsection (a)(1), in the third sentence,
5 by striking “or chapter IX” and inserting “section
6 587R or chapter IX”;

7 (3) in subsection (a)(2)(B)—

8 (A) by inserting “or in vitro clinical tests”
9 after “prescribe or use devices”; and

10 (B) by inserting “or in vitro clinical tests”
11 after “process devices”;

12 (4) by inserting “in vitro clinical test,” after
13 “device,” each place it appears;

14 (5) after making the amendments in para-
15 graphs (1) and (2), by inserting “in vitro clinical
16 tests,” after “devices,” each place it appears;

17 (6) in subsection (e), by inserting “, or section
18 587L, 587M, or 587R,” after “section 519 or
19 520(g)”;

20 (7) in subsection (f)(3)—

21 (A) in subparagraph (A), by striking “or”
22 at the end;

23 (B) in subparagraph (B), by striking the
24 period at the end and inserting “; or”;

1 (C) after subparagraph (B), by inserting
2 the following:

3 “(C) is accredited under section 587P.”.

4 (k) PUBLICITY.—Section 705(b) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
6 by inserting “in vitro clinical tests,” after “devices,”.

7 (l) PRESUMPTION.—Section 709 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
9 inserting “in vitro clinical test,” after “device,”.

10 (m) IMPORTS AND EXPORTS.—Section 801 of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
12 is amended—

13 (1) in subsection (a)—

14 (A) by inserting “in vitro clinical tests,”
15 after “devices,” each place it appears; and

16 (B) by inserting “in the case of an in vitro
17 clinical test, the test does not conform to the
18 applicable requirements of section 587J, or”
19 after “requirements of section 520(f), or”;

20 (2) in subsection (d)(3)—

21 (A) in subparagraph (A)—

22 (i) in the matter preceding clause (i),
23 by inserting “and no component of an in
24 vitro clinical test or other article of in vitro

1 clinical test that requires further proc-
2 essing,” after “health-related purposes”;

3 (ii) in clause (i), by striking “drug or
4 device” and inserting “drug, device, or in
5 vitro clinical test”; and

6 (iii) in clause (i)(I), by inserting “in
7 vitro clinical test,” after “device,”; and

8 (B) in subparagraph (B), by inserting “in
9 vitro clinical test,” after “device,”; and

10 (3) in subsection (e)(1), by inserting “in vitro
11 clinical test,” after “device,”.

12 (n) OFFICE OF INTERNATIONAL RELATIONS.—Sec-
13 tion 803 of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 383) is amended—

15 (1) in subsection (b)—

16 (A) in the matter preceding paragraph (1),
17 by inserting “and in vitro clinical tests” after
18 “devices”; and

19 (B) in paragraph (1), by inserting “quality
20 requirements established under section 587J;
21 and” at the end; and

22 (2) in subsection (c)—

23 (A) in paragraph (2), by inserting “in vitro
24 clinical tests,” after “devices,”; and

1 (B) in paragraph (4), by inserting “or in
2 vitro clinical tests” after “devices”.

3 (o) RECOGNITION OF FOREIGN GOVERNMENT IN-
4 SPECTIONS.—Section 809(a)(1) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-
6 ed by inserting “, or section 587I” after “510(h)”.

7 (p) FOOD AND DRUG ADMINISTRATION.—Section
8 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 393(b)(2)) is amended—

10 (1) in subparagraph (D), by striking “and” at
11 the end;

12 (2) in subparagraph (E), by striking the semi-
13 colon at the end and inserting “; and”; and

14 (3) by adding at the end the following:

15 “(F) in vitro clinical tests are analytically
16 and clinically valid;”.

17 (q) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 399b(b)) is amended—

20 (1) in paragraph (1), by inserting “in vitro clin-
21 ical tests,” after “devices,”; and

22 (2) in paragraph (4), by striking “and device
23 manufacturers” and inserting “device manufactur-
24 ers, and in vitro clinical test developers,”.

1 (r) COUNTERMEASURE PROVISIONS OF THE
2 PHSA.—Title III of the PHSA is amended—

3 (1) in section 319F–2(c)(1)(B) (42 U.S.C.
4 247d–6b(c)(1)(B)) is amended—

5 (A) by striking “or device” and inserting
6 “device”; and

7 (B) by inserting “or an in vitro clinical
8 test (as that term is defined in section 201(ss)
9 of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 321(ss)))” after “Act (21 U.S.C.
11 321(h))”;

12 (2) in section 319F–1(a)(2) (42 U.S.C. 247d–
13 6a(a)(2)), by inserting “an in vitro clinical tests (as
14 that term is defined in section 201(ss) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 321(ss)),” before “or device”; and

17 (3) in section 319F–3(i)(7) (42 U.S.C. 247d–
18 6d(i)(7)), by inserting “an in vitro clinical tests (as
19 that term is defined in section 201(ss) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 321(ss)),” before “or device”.

22 **SEC. 5. TRANSITION.**

23 (a) IMPLEMENTATION.—

24 (1) EFFECTIVE DATE.—

1 (A) IN GENERAL.—Except as otherwise
2 provided in this section, the amendments made
3 by this Act apply 4 years after the date of en-
4 actment of this Act (in this section and in sub-
5 chapter J of chapter V of the Federal Food,
6 Drug, and Cosmetic Act, as added by this Act,
7 referred to in this section as the “effective date
8 of this Act”).

9 (B) EXCEPTION.—The Secretary of Health
10 and Human Services (in this section referred to
11 as the “Secretary”) may take the actions de-
12 scribed in paragraph (2), and may expend such
13 funds as the Secretary determines necessary to
14 ensure an orderly transition.

15 (2) ACTIONS.—The Secretary shall, prior to the
16 date on which the amendments made by this Act
17 generally apply pursuant to paragraph (1)—

18 (A) within 1 year of the date of enactment
19 of this Act hold the public meetings described
20 in subchapter J of chapter V of the Federal
21 Food, Drug, and Cosmetic Act, as added by
22 section 3;

23 (B) within 2 years of the date of enact-
24 ment of this Act promulgate final regulations

1 required under sections 587B, 587D, 587L,
2 587M, 587V, and 587W; and

3 (C) within 2 years of the date of enact-
4 ment of this Act issue final guidance on appli-
5 cability requirements under section 587A.

6 (3) APPLICABILITY OF REGULATIONS.—Not-
7 withstanding the date on which guidance or regula-
8 tions are issued under paragraph (2), no guidance or
9 regulations issued pursuant to the amendments
10 made by this Act shall take effect until the effective
11 date of this Act, as described in paragraph (1), ex-
12 cept as otherwise provided for transitional tests
13 under this section.

14 (b) APPLICATION OF AUTHORITIES TO IN VITRO
15 CLINICAL TESTS UNTIL AND AFTER EFFECTIVE DATE
16 OF THIS ACT.—Except as provided in subsections (c) and
17 (d), for any in vitro clinical test as defined in section
18 201(ss) of the Federal Food, Drug, and Cosmetic Act, as
19 added by this Act, the following authorities shall apply:

20 (1) TESTS OFFERED PRIOR TO ENACTMENT.—

21 An in vitro clinical test that meets the criteria for
22 a grandfathered test as set forth in section
23 587A(c)(2) of the Federal Food, Drug, and Cos-
24 metic Act, as added by section 3, may continue to
25 be offered for clinical use and shall be subject only

1 to applicable provisions of section 353 of the Public
2 Health Service Act and section 587A(a)(4) of the
3 Federal Food, Drug, and Cosmetic Act, as added by
4 section 3.

5 (2) TESTS APPROVED OR CLEARED ON OR
6 AFTER THE DATE OF ENACTMENT BUT PRIOR TO
7 THE EFFECTIVE DATE.—Before any in vitro clinical
8 test as defined in section 201(ss) of the Federal
9 Food, Drug, and Cosmetic Act, as added by this
10 Act, is first offered, sold, or distributed after the
11 date of enactment of this Act, but prior to the effec-
12 tive date of this Act, such product or test shall be
13 considered a transitional test as described under
14 subsection (c) and comply with the applicable device
15 provisions of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 301 et seq.) and the Public Health
17 Service Act (42 U.S.C. 201 et seq.).

18 (3) TESTS UNDER FDA REVIEW BEGINNING ON
19 OR AFTER THE DATE OF ENACTMENT OF THIS ACT
20 BUT PRIOR TO IMPLEMENTATION.—For any in vitro
21 clinical test as defined in section 201(ss) of the Fed-
22 eral Food, Drug, and Cosmetic Act, as added by this
23 Act, for which a submission for marketing authoriza-
24 tion under section 515, clearance under section
25 510(k), authorization under section 513(f)(2), ap-

1 proval under section 520(m), or emergency use au-
2 thorization under section 564 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k),
4 360c(f)(2), 360j(m), 360bbb-3) or approval under
5 the Public Health Service Act (42 U.S.C. 201 et
6 seq.) is pending on the effective date of this Act, the
7 Secretary may review and take action on such sub-
8 mission after the effective date of this Act according
9 to the statutory provision under which such submis-
10 sion was submitted.

11 (c) APPLICATION OF AUTHORITIES TO TRANSI-
12 TIONAL AND GRANDFATHERED IN VITRO CLINICAL
13 TESTS.—

14 (1) DEFINITION.—For purposes of this section,
15 the term “transitional in vitro clinical test” means
16 an in vitro clinical test, as defined in section 201(ss)
17 of the Federal Food, Drug, and Cosmetic Act, as
18 added by this Act, that—

19 (A) is offered for clinical use during the
20 period beginning on the date of enactment of
21 this Act and ending on the date that is 90 days
22 after the effective date of this Act;

23 (B) is developed by a clinical laboratory
24 certified by the Secretary under section 353 of
25 the Public Health Service Act (42 U.S.C. 263a)

1 that meets the requirements for performing
2 high-complexity testing for use only within that
3 certified laboratory or another laboratory within
4 the organization under common ownership; and

5 (C) is not approved under section 515,
6 cleared under section 510(k), authorized under
7 section 513(f)(2), subject to an exemption
8 under section 520(m), or authorized under sec-
9 tion 564 of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360e, 360(k), 360c(f)(2),
11 360j(m), 360bbb-3) or approval under the Pub-
12 lic Health Service Act (42 U.S.C. 201 et seq.).

13 (2) PREMARKET REVIEW OR TECHNOLOGY CER-
14 TIFICATION.—A transitional in vitro clinical test
15 that is the subject of an application for premarket
16 review under section 587B of the Federal Food,
17 Drug, and Cosmetic Act or technology certification
18 application under section 587D of such Act, as
19 added by this Act, that is submitted prior to the ef-
20 fective date of this Act may continue to be offered,
21 sold, or distributed until completion of the Sec-
22 retary's review of the premarket application or tech-
23 nology certification application.

24 (d) CONVERSION.—

1 (1) DEEMED PREMARKET APPROVAL.—Any in
2 vitro clinical test (as defined in section 201(ss) of
3 the Federal Food, Drug, and Cosmetic Act, as
4 added by this Act) with a premarket approval under
5 section 515, a clearance under section 510(k), an
6 authorization under section 513(f), or a licensure
7 under section 351 of the Public Health Service Act
8 (42 U.S.C. 262) is deemed to have an approved ap-
9 plication under section 587B of the Federal Food,
10 Drug, and Cosmetic Act, as added by this Act, be-
11 ginning on the later of—

12 (A) the effective date of this Act; or

13 (B) such other date, not later than 3 years
14 after such effective date, as the person respon-
15 sible for the device selects.

16 (2) DEEMED INVESTIGATIONAL USE AP-
17 PROVAL.—Any in vitro clinical test (as defined in
18 section 201(ss) of the Federal Food, Drug, and Cos-
19 metic Act, as added by this Act) that has an ap-
20 proved investigational device exemption under sec-
21 tion 520(g) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360j(g)) is deemed to have an
23 approved investigational use under section 587Q of
24 such Act, as added by this Act, beginning on the ef-
25 fective date of this Act.

1 (e) INSTRUMENTS.—An instrument (as defined in
2 section 587 of the Federal Food, Drug, and Cosmetic Act,
3 as added by this Act) that was purchased prior to the date
4 of enactment of this Act and was not cleared, authorized,
5 or approved by the Food and Drug Administration or part
6 of an instrument family that was cleared, authorized, or
7 approved by the Food and Drug Administration at the
8 time of purchase may continue to be used by the purchaser
9 to develop and introduce into interstate commerce an in
10 vitro clinical test during the period beginning on the date
11 of enactment of this Act and ending 5 years after such
12 date of enactment. Beginning at the end of such period,
13 any new in vitro clinical test that is developed and intro-
14 duced into interstate commerce shall be based on an in-
15 strument (as defined in section 587(11) of the Federal
16 Food, Drug, and Cosmetic Act, as added by section 3)
17 that complies with the requirements of the Federal Food,
18 Drug, and Cosmetic Act, as amended by this Act.

19 (f) RELATION TO IN VITRO CLINICAL TEST PROVI-
20 SION.—This section applies notwithstanding section
21 587A(a)(1)(C) of the Federal Food, Drug, and Cosmetic
22 Act, as added by this Act.

23 **SEC. 6. EMERGENCY USE AUTHORIZATION.**

24 Section 564 of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 360bbb–3) is amended—

1 (1) in paragraphs (1) and (4)(C) of subsection
2 (a), by inserting “in vitro clinical test,” before “or
3 biological product” each place such term appears;
4 and

5 (2) in subsection (e)(3)—

6 (A) in subparagraph (B), by striking
7 “and” at the end;

8 (B) in subparagraph (C), by striking the
9 period and inserting “; and”; and

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

11 “(D) quality system requirements (with re-
12 spect to in vitro clinical tests) under section
13 587J.”.

14 **SEC. 7. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

15 Section 511A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 360a-2) is amended—

17 (1) in subsection (a)(1)(C)—

18 (A) by striking “or approve under section
19 515” and inserting “approve under section 515,
20 or approve, exempt, or issue a technology cer-
21 tification order under subchapter J”; and

22 (B) by striking “testing devices” and in-
23 serting “tests”;

1 (2) in subsection (c)(5), by striking “drug or
2 device” each place it appears and inserting “drug,
3 device, or in vitro clinical test”;

4 (3) in subsection (e)—

5 (A) in the heading, by striking “TESTING
6 DEVICES” and inserting “IN VITRO CLINICAL
7 TESTS”;

8 (B) in paragraph (1)—

9 (i) by striking “and 515,” and insert-
10 ing “515, 587B, and 587D”;

11 (ii) by striking “antimicrobial suscep-
12 tibility testing device” and inserting “anti-
13 microbial susceptibility in vitro clinical
14 test”; and

15 (iii) by striking “such device” and in-
16 serting “such test”;

17 (C) in paragraph (2)—

18 (i) in the heading, by striking “TEST-
19 ING DEVICES” and inserting “IN VITRO
20 CLINICAL TESTS”; and

21 (ii) by amending subparagraph (C) to
22 read as follows:

23 “(C) The antimicrobial susceptibility in
24 vitro clinical test meets all other requirements
25 to be approved under section 587B or exempted

1 from premarket review under section 587D.”;
2 and

3 (D) after making the amendments in sub-
4 paragraphs (B)(ii), (B)(iii), and (C)(ii), by
5 striking “device” each place it appears and in-
6 serting “in vitro clinical test”;

7 (4) in subsection (f), by amending paragraph
8 (1) to read as follows:

9 “(1) The term ‘antimicrobial susceptibility in
10 vitro clinical test’ means an in vitro clinical test that
11 utilizes susceptibility test interpretive criteria to de-
12 termine and report the in vitro susceptibility of cer-
13 tain microorganisms to a drug (or drugs).”; and

14 (5) in subsection (g)(2)—

15 (A) by amending the matter preceding sub-
16 paragraph (A) to read as follows:

17 “(2) with respect to clearing under section
18 510(k), classifying under section 513(f)(2), approv-
19 ing under section 515 or section 587B, or exempting
20 from approval requirements under section 587D—”;
21 and

22 (B) in subparagraph (A)—

23 (i) by striking “device” and inserting
24 “in vitro clinical test”; and

1 (ii) by striking “antimicrobial suscep-
2 tibility testing device” and inserting “anti-
3 microbial susceptibility in vitro clinical
4 test”.

5 **SEC. 8. COMBINATION PRODUCTS.**

6 (a) IN GENERAL.—Section 503(g) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is
8 amended—

9 (1) in paragraph (1)—

10 (A) in subparagraph (A)—

11 (i) by inserting “(except for a com-
12 bination product constituted of a device
13 and an in vitro clinical test)” after “agency
14 center,”; and

15 (ii) by inserting “in vitro clinical
16 test,” before “or biological product”; and

17 (B) in subparagraph (D)—

18 (i) in the matter preceding clause (i),
19 by striking “. If the Secretary determines”
20 and inserting “, except for a combination
21 product constituted of a device and an in
22 vitro clinical test. For other combination
23 products, if the Secretary determines”; and

24 (ii) in clause (ii)—

1 (I) by inserting “or in vitro clin-
2 ical test” after “device”; and

3 (II) by inserting “and in vitro
4 clinical tests” before “shall”;

5 (2) in paragraph (3), by striking “safety and
6 effectiveness or substantial equivalence” and insert-
7 ing “safety and effectiveness, substantial equiva-
8 lence, or analytical validity and clinical validity” be-
9 fore “for the approved constituent part”;

10 (3) in paragraph (4)—

11 (A) in subparagraph (A), by striking “or
12 513(f)(2) (submitted in accordance with para-
13 graph (5))” and inserting “513(f)(2) (sub-
14 mitted in accordance with paragraph (5)),
15 587B, or an exempt test under section 587A, as
16 applicable”; and

17 (B) in subparagraph (B), by inserting “or
18 587B” after “section 515”;

19 (4) in paragraph (5)(A), by striking “or
20 510(k)” and inserting “, 510(k), or 587B”;

21 (5) in paragraph (7), by striking “or substan-
22 tial equivalence” and inserting “, substantial equiva-
23 lence, or analytical validity and clinical validity”;

24 (6) in paragraph (8), by adding at the end the
25 following:

1 “(I) This paragraph shall not apply to a
2 combination product constituted of a device and
3 an in vitro clinical test.”; and

4 (7) in paragraph (9)—

5 (A) in subparagraph (C)(i), by striking “or
6 520(g)” and inserting “520(g), or 587B”; and

7 (B) in subparagraph (D), by striking “or
8 520” and inserting “520, or 587B”.

9 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 360bbb–2) is amended by adding at the end the following:

12 “(d) EXEMPTION.—This section shall not apply to a
13 combination product constituted of a device and an in
14 vitro clinical test.”.

15 **SEC. 9. RESOURCES.**

16 (a) FINDINGS.—Congress finds that the fees author-
17 ized by this section will be dedicated to meeting the goals
18 identified in the letters from the Secretary of Health and
19 Human Services to the Committee on Health, Education,
20 Labor, and Pensions of the Senate and the Committee on
21 Energy and Commerce of the House of Representatives,
22 as set forth in the Congressional Record.

23 (b) ESTABLISHMENT OF USER FEE PROGRAM.—

24 (1) DEVELOPMENT OF USER FEES FOR IN
25 VITRO CLINICAL TESTS.—

1 (A) IN GENERAL.—Beginning not later
2 than October 1, 2021, the Secretary of Health
3 and Human Services (in this section referred to
4 as the “Secretary”) shall develop recommenda-
5 tions to present to Congress with respect to the
6 goals, and plans for meeting the goals, for the
7 process of the review of in vitro clinical test ap-
8 plications submitted under subchapter J of
9 chapter V of the Federal Food, Drug, and Cos-
10 metic Act, as added by this Act, for the first 5
11 fiscal years after fiscal year 2022. In developing
12 such recommendations, the Secretary shall con-
13 sult with—

14 (i) the Committee on Energy and
15 Commerce of the House of Representa-
16 tives;

17 (ii) the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate;

19 (iii) scientific and academic experts;

20 (iv) health care professionals;

21 (v) representatives of patient and con-
22 sumer advocacy groups; and

23 (vi) the regulated industry.

24 (B) PRIOR PUBLIC INPUT.—Prior to begin-
25 ning negotiations with the regulated industry

1 on the authorization of such subchapter J, the
2 Secretary shall—

3 (i) publish a notice in the Federal
4 Register requesting public input on the au-
5 thorization of user fees;

6 (ii) hold a public meeting at which the
7 public may present its views on the author-
8 ization, including specific suggestions for
9 the recommendations submitted under sub-
10 paragraph (E);

11 (iii) provide a period of 30 days after
12 the public meeting to obtain written com-
13 ments from the public suggesting changes
14 to such subchapter J; and

15 (iv) publish any comments received
16 under clause (iii) on the website of the
17 Food and Drug Administration.

18 (C) PERIODIC CONSULTATION.—Not less
19 frequently than once every month during nego-
20 tiations with the regulated industry, the Sec-
21 retary shall hold discussions with representa-
22 tives of patient and consumer advocacy groups
23 to continue discussions of the authorization
24 under such subchapter J and to solicit sugges-
25 tions to be included in the recommendations

1 transmitted to Congress under subparagraph
2 (E).

3 (D) PUBLIC REVIEW OF RECOMMENDA-
4 TIONS.—After negotiations with the regulated
5 industry, the Secretary shall—

6 (i) present the recommendations de-
7 veloped under subparagraph (A) to the
8 Committee on Health, Education, Labor,
9 and Pensions of the Senate and the Com-
10 mittee on Energy and Commerce of the
11 House of Representatives;

12 (ii) publish such recommendations in
13 the Federal Register;

14 (iii) provide for a period of 30 days
15 for the public to provide written comments
16 on such recommendations;

17 (iv) hold a meeting at which the pub-
18 lic may present its views on such rec-
19 ommendations; and

20 (v) after consideration of such public
21 views and comments, revise such rec-
22 ommendations as necessary.

23 (E) TRANSMITTAL OF RECOMMENDA-
24 TIONS.—

1 (i) IN GENERAL.—Not later than
2 June 1, 2021, the Secretary shall transmit
3 to Congress the revised recommendations
4 under subparagraph (A), a summary of the
5 views and comments received under such
6 subparagraph, and any changes made to
7 the recommendations in response to such
8 views and comments.

9 (ii) RECOMMENDATION REQUIRE-
10 MENTS.—The recommendations trans-
11 mitted under this subparagraph shall—

12 (I) include the number of full-
13 time equivalent employees per fiscal
14 year that are agreed to be hired to
15 carry out the goals included in such
16 recommendations for each year of the
17 5-year period;

18 (II) provide that the amount of
19 operating reserve balance in the user
20 fee program established under this
21 section is not more than the equiva-
22 lent of 10 weeks of operating reserve;

23 (III) require the development of
24 a strategic plan for any surplus within
25 the operating reserve account above

1 the 10-week operating reserve within
2 2 years of the establishment of the
3 program;

4 (IV) include an operating reserve
5 adjustment such that, if the Secretary
6 has an operating reserve balance in
7 excess of 10 weeks of such operating
8 reserves, the Secretary shall decrease
9 such fee revenue and fees to provide
10 for not more than 10 weeks of such
11 operating reserves;

12 (V) if an adjustment is made as
13 described in subclause (IV), provide
14 the rationale for the amount of the
15 decrease in fee revenue and fees shall
16 be contained in the Federal Register;
17 and

18 (VI) provide that the fees as-
19 sessed and collected for the full-time
20 equivalent employees at the Center for
21 Devices and Radiological Health, with
22 respect to which the majority of time
23 reporting data indicates are dedicated
24 to the review of in vitro clinical tests,
25 are not supported by the funds au-

1 (ii) CONTENT.—The minutes de-
2 scribed under clause (i) shall summarize
3 any substantive proposal made by any
4 party to the negotiations, any significant
5 controversies or differences of opinion dur-
6 ing the negotiations, and the resolution of
7 any such controversy or difference of opin-
8 ion.

9 (2) ESTABLISHMENT OF USER FEE PRO-
10 GRAM.—Effective on October 1, 2021, provided that
11 the Secretary transmits the recommendations under
12 paragraph (1)(E), the Secretary is authorized to col-
13 lect user fees relating to the submission of in vitro
14 clinical test applications submitted under subchapter
15 J of chapter V of the Federal Food, Drug, and Cos-
16 metic Act, as added by this Act. Fees under such
17 program shall be assessed and collected only if the
18 requirements under paragraph (4) are met.

19 (3) AUDIT.—

20 (A) IN GENERAL.—On the date that is 2
21 years after first receiving a user fee applicable
22 to submission of an in vitro clinical test applica-
23 tion submitted under subchapter J of chapter V
24 of the Federal Food, Drug, and Cosmetic Act,
25 as added by this Act, and on a biennial basis

1 thereafter until October 1, 2027, the Secretary
2 shall perform an audit of the costs of reviewing
3 such applications under such subchapter J.
4 Such an audit shall compare the costs of re-
5 viewing such applications under such sub-
6 chapter J to the amount of the user fee applica-
7 ble to such applications.

8 (B) ALTERATION OF USER FEE.—If the
9 audit performed under subparagraph (A) indi-
10 cates that the user fees applicable to applica-
11 tions submitted under such subchapter J exceed
12 30 percent of the costs of reviewing such appli-
13 cations, the Secretary shall alter the user fees
14 applicable to applications submitted under such
15 subchapter J such that the user fees do not ex-
16 ceed such percentage.

17 (C) ACCOUNTING STANDARDS.—The Sec-
18 retary shall perform an audit under subpara-
19 graph (A) in conformance with the accounting
20 principles, standards, and requirements pre-
21 scribed by the Comptroller General of the
22 United States under section 3511 of title 31,
23 United States Code, to ensure the validity of
24 any potential variability.

1 (4) CONDITIONS.—The user fee program de-
2 scribed in this subsection shall take effect only if the
3 Food and Drug Administration issues draft guidance
4 related to the review requirements for in vitro diag-
5 nostic tests that would be subject to premarket re-
6 view under section 587B of the Federal Food, Drug,
7 and Cosmetic Act, as added by section 3, the review
8 requirements for test categories eligible for tech-
9 nology certification under section 587D of such Act,
10 as added by section 3, and the parameters for the
11 test categories that would be exempt from any re-
12 view under subchapter J of chapter V of such Act.

13 (5) USER FEE PROGRAM DEFINITIONS AND RE-
14 SOURCE REQUIREMENTS.—

15 (A) IN GENERAL.—The term “process for
16 the review of in vitro clinical test applications”
17 means the following activities of the Secretary
18 with respect to the review of premarket applica-
19 tions under section 587B of the Federal Food,
20 Drug, and Cosmetic Act (as added by section
21 3), technology certification applications under
22 section 587D of such Act (as added by section
23 3), and supplements for such applications:

24 (i) The activities necessary for the re-
25 view of premarket applications, premarket

1 reports, and supplements to such applica-
2 tions.

3 (ii) The issuance of action letters that
4 allow the marketing of in vitro clinical
5 tests or which set forth in detail the spe-
6 cific deficiencies in such applications, re-
7 ports, supplements, or submissions and,
8 where appropriate, the actions necessary to
9 place them in condition for approval.

10 (iii) The inspection of manufacturing
11 establishments and other facilities under-
12 taken as part of the Secretary's review of
13 pending premarket applications, technology
14 certifications, and supplements.

15 (iv) Monitoring of research conducted
16 in connection with the review of such appli-
17 cations, supplements, and submissions.

18 (v) Review of in vitro clinical test ap-
19 plications subject to section 351 of the
20 Public Health Service Act (42 U.S.C.
21 262), investigational new drug applications
22 under section 505(i) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C.
24 355(i)), or investigational test exemptions
25 under section 587A(m) of the Federal

1 Food, Drug, and Cosmetic Act (as added
2 by section 3), and activities conducted in
3 anticipation of the submission of such ap-
4 plications under section 505(i) of the Fed-
5 eral Food, Drug, and Cosmetic Act or in-
6 vestigational use under section 587R of the
7 Federal Food, Drug, and Cosmetic Act (as
8 added by section 3).

9 (vi) The development of guidance, pol-
10 icy documents, or regulations to improve
11 the process for the review of premarket ap-
12 plications, technology certification applica-
13 tions, and supplements.

14 (vii) The development of voluntary
15 test methods, consensus standards, or
16 mandatory performance standards in con-
17 nection with the review of such applica-
18 tions, supplements, or submissions and re-
19 lated activities.

20 (viii) The provision of technical assist-
21 ance to in vitro clinical test developers in
22 connection with the submission of such ap-
23 plications, reports, supplements, or submis-
24 sions.

1 (ix) Any activity undertaken in con-
2 nection with the initial classification or re-
3 classification of an in vitro clinical test in
4 connection with any requirement for ap-
5 proval of an in vitro clinical test.

6 (x) Evaluation of postmarket studies
7 required as a condition of an approval of
8 a premarket application of an in vitro clin-
9 ical test.

10 (xi) Compiling, developing, and re-
11 viewing information on relevant in vitro
12 clinical tests to identify issues with the ap-
13 plicable standard for premarket applica-
14 tions, technology certification applications,
15 and supplements.

16 (B) RESOURCE REQUIREMENTS.—Fees col-
17 lected and assessed under this section shall be
18 used for the process for the review of in vitro
19 clinical test applications, as described in sub-
20 paragraph (A), and shall—

21 (i) be subject to the limitation under
22 section 738(g)(3) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C.
24 379j(g)(3)), in the same manner that fees
25 collected and assessed under section

1 737(9)(C) of such Act (21 U.S.C.
2 379i(9)(C)) are subject to such limitation;

3 (ii) include travel expenses for officers
4 and employees of the Food and Drug Ad-
5 ministration only if the Secretary deter-
6 mines that such travel is directly related to
7 an activity described in subparagraph (A);
8 and

9 (iii) not be allocated to purposes de-
10 scribed under section 722(a) of the Con-
11 solidated Appropriations Act, 2018 (Public
12 Law 115–141).

13 (c) REPORTS.—

14 (1) PERFORMANCE REPORT.—

15 (A) IN GENERAL.—

16 (i) GENERAL REQUIREMENTS.—Be-
17 ginning with fiscal year 2021, for each fis-
18 cal year for which fees are collected under
19 this section, the Secretary shall prepare
20 and submit to the Committee on Health,
21 Education, Labor, and Pensions of the
22 Senate and the Committee on Energy and
23 Commerce of the House of Representatives
24 annual reports concerning the progress of
25 the Food and Drug Administration in

1 achieving the goals identified in the rec-
2 ommendations transmitted to Congress by
3 the Secretary pursuant to subsection
4 (b)(1)(E) during such fiscal year and the
5 future plans of the Food and Drug Admin-
6 istration for meeting the goals.

7 (ii) ADDITIONAL INFORMATION.—Be-
8 ginning with fiscal year 2021, the annual
9 report under this subparagraph shall in-
10 clude the progress of the Food and Drug
11 Administration in achieving the goals, and
12 future plans for meeting the goals, includ-
13 ing—

14 (I) the number of premarket ap-
15 plications filed under section 587B of
16 the Federal Food, Drug, and Cos-
17 metic Act during the applicable fiscal
18 year;

19 (II) the number of technology
20 certification applications submitted
21 under section 587D of the Federal
22 Food, Drug, and Cosmetic Act during
23 the applicable fiscal year for each re-
24 view division; and

1 (III) the number of breakthrough
2 designations under section 587C of
3 the Federal Food, Drug, and Cos-
4 metic Act during the applicable fiscal
5 year.

6 (iii) REAL-TIME REPORTING.—

7 (I) IN GENERAL.—Not later than
8 30 calendar days after the end of the
9 second quarter of fiscal year 2021,
10 and not later than 30 calendar days
11 after the end of each quarter of each
12 fiscal year thereafter, the Secretary
13 shall post the data described in sub-
14 clause (II) on the website of the Food
15 and Drug Administration for such
16 quarter and on a cumulative basis for
17 such fiscal year, and may remove du-
18 plicative data from the annual report
19 under this subparagraph.

20 (II) DATA.—The Secretary shall
21 post the following data in accordance
22 with subclause (I):

23 (aa) The number and titles
24 of draft and final guidance on
25 topics related to the process for

1 the review of in vitro clinical
2 tests, and whether such guid-
3 ances were issued as required by
4 statute or pursuant to the rec-
5 ommendations transmitted to
6 Congress by the Secretary pursu-
7 ant to subsection (b)(1)(E).

8 (bb) The number and titles
9 of public meetings held on topics
10 related to the process for the re-
11 view of in vitro clinical tests, and
12 if such meetings were required by
13 statute or pursuant to the rec-
14 ommendations transmitted to
15 Congress by the Secretary pursu-
16 ant to subsection (b)(1)(E).

17 (iv) RATIONALE FOR IVCT USER FEE
18 PROGRAM CHANGES.—Beginning with fis-
19 cal year 2022, the Secretary shall include
20 in the annual performance report under
21 paragraph (1)—

22 (I) data, analysis, and discussion
23 of the changes in the number of full-
24 time equivalents hired as agreed upon
25 in the recommendations transmitted

1 to Congress by the Secretary pursuant
2 to subsection (b)(1)(E) and the num-
3 ber of full-time equivalents funded by
4 budget authority at the Food and
5 Drug Administration by each division
6 within the Center for Devices and Ra-
7 diological Health, the Center for Bio-
8 logics Evaluation and Research, the
9 Office of Regulatory Affairs, and the
10 Office of the Commissioner;

11 (II) data, analysis, and discus-
12 sion of the changes in the fee revenue
13 amounts and costs for the process for
14 the review of in vitro clinical tests, in-
15 cluding identifying drivers of such
16 changes; and

17 (III) for each of the Center for
18 Devices and Radiological Health, the
19 Center for Biologics Evaluation and
20 Research, the Office of Regulatory Af-
21 fairs, and the Office of the Commis-
22 sioner, the number of employees for
23 whom time reporting is required and
24 the number of employees for whom
25 time reporting is not required.

1 (v) ANALYSIS.—For each fiscal year,
2 the Secretary shall include in the report
3 under clause (i) an analysis of the fol-
4 lowing:

5 (I) The difference between the
6 aggregate number of premarket appli-
7 cations filed under section 587B or
8 section 587D of the Federal Food,
9 Drug, and Cosmetic Act and the ag-
10 gregate number of major deficiency
11 letters, not approvable letters, and de-
12 nials for such applications issued by
13 the agency, accounting for—

14 (aa) the number of applica-
15 tions filed under each of sections
16 587B and 587D of the Federal
17 Food, Drug, and Cosmetic Act
18 during one fiscal year for which a
19 decision is not scheduled to be
20 made until the following fiscal
21 year; and

22 (bb) the aggregate number
23 of applications under each of sec-
24 tions 587B and 587D of the
25 Federal Food, Drug, and Cos-

1 metic Act for each fiscal year
2 that did not meet the goals as
3 identified by the recommenda-
4 tions transmitted to Congress by
5 the Secretary pursuant to sub-
6 section (b)(1)(E).

7 (II) Relevant data to determine
8 whether the Center for Devices and
9 Radiological Health has met perform-
10 ance enhancement goals identified by
11 the recommendations transmitted to
12 Congress by the Secretary pursuant to
13 subsection (b)(1)(E).

14 (III) The most common causes
15 and trends for external or other cir-
16 cumstances affecting the ability of the
17 Food and Drug Administration to
18 meet review time and performance en-
19 hancement goals identified by the rec-
20 ommendations transmitted to Con-
21 gress by the Secretary pursuant to
22 subsection (b)(1)(E).

23 (B) PUBLICATION.—With regard to infor-
24 mation to be reported by the Food and Drug
25 Administration to industry on a quarterly and

1 annual basis pursuant to recommendations
2 transmitted to Congress by the Secretary pur-
3 suant to subsection (b)(1)(E), the Secretary
4 shall make such information publicly available
5 on the website of the Food and Drug Adminis-
6 tration not later than 60 days after the end of
7 each quarter or 120 days after the end of each
8 fiscal year, respectively, to which such informa-
9 tion applies.

10 (C) UPDATES.—The Secretary shall in-
11 clude in each report under subparagraph (A)
12 information on all previous cohorts for which
13 the Secretary has not given a complete response
14 on all in vitro clinical test premarket applica-
15 tions and technology certification orders and
16 supplements, premarket, and technology certifi-
17 cation notifications in the cohort.

18 (2) CORRECTIVE ACTION REPORT.—Beginning
19 with fiscal year 2022, for each fiscal year for which
20 fees are collected under this section, the Secretary
21 shall prepare and submit a corrective action report
22 to the Committee on Health, Education, Labor, and
23 Pensions and the Committee on Appropriations of
24 the Senate and the Committee on Energy and Com-
25 merce and the Committee on Appropriations of the

1 House of Representatives. The report shall include
2 the following information, as applicable:

3 (A) GOALS MET.—For each fiscal year, if
4 the Secretary determines, based on the analysis
5 under paragraph (1)(A)(v), that each of the
6 goals identified by the recommendations trans-
7 mitted to Congress by the Secretary pursuant
8 to subsection (b)(1)(E) for the applicable fiscal
9 year have been met, the corrective action report
10 shall include recommendations on ways in which
11 the Secretary can improve and streamline the in
12 vitro clinical test premarket application and
13 technology certification review process.

14 (B) GOALS MISSED.—For each of the goals
15 identified by the letters described in rec-
16 ommendations transmitted to Congress by the
17 Secretary pursuant to subsection (b)(1)(E) for
18 the applicable fiscal year that the Secretary de-
19 termines to not have been met, the corrective
20 action report shall include—

21 (i) a justification for such determina-
22 tion;

23 (ii) a description of the types of cir-
24 cumstances, in the aggregate, under which
25 applications or reports submitted under

1 sections 587B and 587D of the Federal
2 Food, Drug, and Cosmetic Act missed the
3 review goal times but were approved dur-
4 ing the first cycle review, as applicable;

5 (iii) a summary and any trends with
6 regard to the circumstances for which a re-
7 view goal was missed; and

8 (iv) the performance enhancement
9 goals that were not achieved during the
10 previous fiscal year and a description of ef-
11 forts the Food and Drug Administration
12 has put in place for the fiscal year in
13 which the report is submitted to improve
14 the ability of such agency to meet each
15 such goal for the such fiscal year.

16 (3) FISCAL REPORT.—For fiscal years 2021
17 and annually thereafter, not later than 120 days
18 after the end of each fiscal year during which fees
19 are collected under this subpart, the Secretary shall
20 prepare and submit to the Committee on Health,
21 Education, Labor, and Pensions of the Senate and
22 the Committee on Energy and Commerce of the
23 House of Representatives, a report on the implemen-
24 tation of the authority for such fees during such fis-
25 cal year and the use, by the Food and Drug Admin-

1 istration, of the fees collected during such fiscal year
2 for which the report is made.

3 (A) CONTENTS.—Such report shall include
4 expenditures delineated by budget authority and
5 user fee dollars related to administrative ex-
6 penses and information technology infrastruc-
7 ture contracts and expenditures.

8 (B) OPERATING RESERVE.—Such report
9 shall provide the amount of operating reserve
10 balance available each year, and any planned al-
11 locations or obligations of such balance that is
12 above 10 weeks of operating reserve for the pro-
13 gram.

14 (4) PUBLIC AVAILABILITY.—The Secretary
15 shall make the reports required under paragraphs
16 (1) through (3) available to the public on the website
17 of the Food and Drug Administration.

18 (5) ENHANCED COMMUNICATION.—

19 (A) COMMUNICATIONS WITH CONGRESS.—
20 Each fiscal year, as applicable and requested,
21 representatives from the Centers with expertise
22 in the review of in vitro clinical tests shall meet
23 with representatives from the Committee on
24 Health, Education, Labor, and Pensions of the
25 Senate and the Committee on Energy and Com-

1 merce of the House of Representatives to report
2 on the contents described in the reports under
3 this section.

4 (B) PARTICIPATION IN CONGRESSIONAL
5 HEARING.—Each fiscal year, as applicable and
6 requested, representatives from the Food and
7 Drug Administration shall participate in a pub-
8 lic hearing before the Committee on Health,
9 Education, Labor, and Pensions of the Senate
10 and the Committee on Energy and Commerce
11 of the House of Representatives, to report on
12 the contents described in the reports under this
13 section. Such hearing shall occur not later than
14 120 days after the end of each fiscal year for
15 which fees are collected under this section.