Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


Dear Sir or Madame:

The Advanced Medical Technology Association (“AdvaMed”) welcomes the opportunity to provide comments on the Food and Drug Administration (“FDA” or “Agency”) draft guidance, Process to Request a Review of FDA’s Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff (“Draft CFG Guidance”).

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed’s member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed’s member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments.

While AdvaMed appreciates FDA’s timely publication of the Draft CFG Guidance, we note that it suffers from inaccuracies and omissions that FDA must correct. In particular: (1) in refusing to issue CFGs for devices exported from outside the U.S., the draft guidance contradicts express Congressional intent; (2) the draft guidance’s process for handling denials of CFGs suffers from critical gaps; (3) the draft guidance’s process for reviewing CFG denials does not satisfy FDARA section 704’s mandate for a process “that conforms to the standards of [FDCA] section 517A(b)”; and (4) in publishing the guidance, FDA has failed to correct inconsistencies within its current certification process. We detail these deficiencies below and in the comments that follow relating to specific parts of the draft guidance.
The Draft CFG Guidance’s position that FDA will not issue CFGs for devices outside the United States contradicts explicit Congressional instruction.

In the scope section of the Draft CFG Guidance, FDA proposes to exclude from eligibility all devices that are not exported from the U.S. FDA asserts that it will answer a request for a CFG for such devices by “notify[ing] the submitter . . . that the device is ineligible for consideration for an export certificate because it is outside the scope of section 801(e)(4)(A).”\(^1\) FDA’s position is plainly incorrect, and excluding all such devices from CFG eligibility would be arbitrary and capricious, inconsistent with current agency policy, and disregard Congress’s undisputed intent in FDARA section 704.

Section 704 provides that, whenever FDA denies a request for certification for a device manufactured in any foreign or domestic FDA-registered establishment, the agency shall provide an explanation for the denial.\(^2\) Under Section 704, certain conditions are not proper bases for a denial, and parties denied a CFG must have an opportunity for review. Section 704 further explains that it “applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located inside or outside the U.S., and regardless of whether such devices are to be exported from the United States.”\(^3\)

Thus, by its terms, FDARA imposes a comprehensive structure for explaining and reviewing CFG denials, and it emphasizes that this structure applies to device establishments “regardless of whether” the devices are exported from the U.S. FDA’s proposed approach ignores this explicit order from Congress. The Draft CFG Guidance requires imagining that Congress went to the trouble of passing a federal law authorizing establishments to apply for CFGs, and that FDA then undertook the meaningless exercise of explaining the grounds for denial and providing a review of the denial, even though the establishments could never obtain the sought-after certification.\(^4\) This reading subverts Congress’s obvious intent for CFGs to be available to foreign establishments, even if they do not export devices from the U.S.\(^5\) Indeed, FDA’s approach renders superfluous

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\(^1\) Draft CFG Guidance, lines 113-116
\(^2\) FDARA section 704 (adding section (E)(i)(I) to 21 U.S.C. 381(e)(4))
\(^3\) FDARA Section 704 (adding FDCA Section 801(e)(4)(E)(iii)(I) to 21 U.S.C. 381(e)(4)) (emphasis added)
\(^4\) Section 704 requires FDA to provide for any CFG denial the “basis for such denial, and specifically identify the finding upon which such denial is based.” FDARA section 704 (adding section (E)(i)(I) to 21 U.S.C. 381(e)(4)). This directive confirms that the grounds for a denial for any foreign or domestic FDA-registered device establishment are to be a “finding,” not a categorical exclusion.

\(^5\) “Deference to administrative policy-making is not so great as to reduce our role to rubber-stamping regulations that are “inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.”” NLRB v. Brown, 380 U.S. 278, 291–92 (1965). If the Secretary’s regulations implementing the [Family and Medical Leave Act] subvert congressional intent to a degree that renders the regulations arbitrary, we are obliged to declare them inconsistent with the statute.” Miller v. AT&T Corp.,
section 704’s critical statement that it applies “regardless of whether” the devices are exported from the U.S.\(^6\) FDA provides no explanation or plausible alternative that would give this Congressional directive any meaning or effect.

FDA characterizes FDCA section 801(e)(4)(A) as applying to “export certificates,” but not to devices exported from outside the U.S. (OUS).\(^7\) The Agency apparently believes that its newly-announced restriction justifies ignoring the plain meaning of FDARA section 704. That provision’s addition of subparagraph 801(e)(4)(E)(iii) clarifies that certifications granted under subparagraph (A) are not restricted to products exported from the U.S. Notably, when Congress was considering FDARA, FDA already granted (and continues to grant) certificates for products exported from outside the U.S. Under the “Export Certificate Program” for drugs, FDA grants certificates for drugs that are “exported from one foreign country to another.”\(^8\) It is well understood that FDA does not limit export certificates to exports from \textit{within} the U.S.\(^9\) In other words, when Congress passed FDARA, FDA willingly interpreted “exports” to incorporate exports from

\(^{250}\) F.3d 820, 833 (4th Cir. 2001) (citing Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 843 n.9 (1984)).

\(^{6}\) See Corley v. United States, 556 U.S. 303, 304 (2009) (“The Government’s reading renders [a statutory provision] nonsensical and superfluous. . . . The Government’s reading is thus at odds with the basic interpretive canon that a statute should be construed \textit{to give effect to all its provisions, so that no part will be inoperative or void, or insignificant.}” (citation and internal quotation marks omitted, emphasis added); Marx v. Gen. Revenue Corp., 568 U.S. 371, 373 (2013) (“The canon [against surplusage] is strongest when an interpretation would render superfluous another part of the same statutory scheme.”);

\(^{7}\) Draft CFG Guidance, line 113


\(^{9}\) It is also worth considering the implications of FDA’s position that CDRH lacks the authority to issue CFGs for devices exported from outside the U.S., while CDER regularly grants these certificates. CDER plainly states that it proceeds under authority granted by FDCA section 801. See, e.g., https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/importsandexportscompliance/ucm48825.htm (“FDA issues export certificates for approved or licensed drugs and for unapproved drugs that meet the requirements of Sections 801(e)(1) or 802 of the FD&C Act.”). How is it that section 801, which specifically references certificates for drugs \textit{and} devices, permits CDER to issue certificates for OUS drugs, but prevents CDRH from issuing CFGs for OUS devices? Does CDER have authority that CDRH lacks? Is CDER operating illegally, while CDRH follows the law? The answer to both questions, obviously, is no. Like CDER, CDRH has always had authority to issue CFGs for OUS devices. FDARA section 704 memorializes this authority and directs CDRH to take certain steps when it denies CFGs.
countries outside the U.S.; in FDARA section 704, Congress directs FDA to do the same for qualifying device establishments.

FDA likewise fails to account for FDARA section 704’s exclusion of some device establishments from eligibility for CFGs when exporting devices from outside the U.S. Under section 704, an establishment outside the U.S. that cannot “demonstrate that the devices manufactured, prepared, propagated, compounded, or processed at such establishment are to be exported from the U.S.,” is eligible for a CFG only if it has been inspected either by FDA or a U.S.-recognized audit program within three years of the request. 10 Again, FDA’s plainly erroneous interpretation requires believing that Congress chose to add language to the FDCA that has no purpose at all, as there would be no reason to assess whether an establishment was inspected in the last three years if it could not obtain a CFG anyway. The only sensible interpretation is that inclusion of the three-year criteria confirms that establishments that have been inspected within this timeframe are indeed eligible to receive CFGs.11

FDA engaged directly with Congress and other stakeholders in negotiating section 704, and FDA knew that this provision was intended to confirm that foreign establishments in good standing with FDA could obtain CFGs. So, it is particularly puzzling that FDA now excludes CFGs for OUS facilities since it was FDA that suggested the inspection criteria that Congress included for these establishments. FDA presumably offered these criteria in good faith, rather than to saddle the FDCA with language that FDA considers superfluous.

FDA’s failure to follow clear Congressional direction, and to adopt a practice used elsewhere in the Agency, is a mystery – and the Draft CFG Guidance does not offer any answers. Put simply, FDA now needs to fix the problems that it created; the Agency must revise the draft guidance to clarify that, consistent with FDARA section 704, it will issue CFGs for OUS devices.

**FDA should revise section III of the Draft CFG Guidance to close significant gaps.**

10 FDARA Section 704 (adding FDCA Section 801(e)(4)(E)(iii)(II) to 21 U.S.C. 381(e)(4))
11 “It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. A court must therefore interpret the statute as a symmetrical and coherent regulatory scheme and fit, if possible, all parts into an harmonious whole.” FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132–133 (2000) (citations and internal quotation marks omitted). See also Bureau of Alcohol, Tobacco & Firearms v. Fed. Labor Relations Auth., 464 U.S. 89, 97 (1983) (“While reviewing courts should uphold reasonable and defensible constructions of an agency's enabling Act, they must not ‘rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.’”) (quoting NLRB v. Brown, 380 U.S. 278, 291–92 (1965)) (additional citation omitted).
In detailing FDA’s process for denials of CFG requests, section III suffers from three serious deficiencies: (1) the standard for agreeing on a plan of correction is overly restrictive; (2) there is inadequate information about submission of a plan of correction; and (3) there is inadequate information about the summary of the specific grounds for noncompliance.

Turning first to the standard for an agreed plan of correction, FDARA section 704 provides that FDA “shall not deny a request for certification . . . with respect to a device based solely on the issuance of . . . [a] report [under FDCA section 704(b)] if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.”\(^\text{12}\) The Draft CFG Guidance, in turn, requires FDA and the establishment “owner, operator, or agent in charge” to agree on a correction plan that is “sufficient to address the violations documented in the inspectional observations.”\(^\text{13}\)

This standard is inappropriately narrow and will result in few, if any, CFGs following an inspectional report under FDCA section 704(b). Before a correction plan is underway, it is essentially impossible to know if it will sufficiently address the violations documented in inspectional observations. Indeed, many correction plans change because the manufacturer recognizes that parts of the plan will not fully resolve the violations. This dynamic process is critical to assure that correction plans are tested while underway and, when needed, modified. By contrast, to demand certainty at the outset requires FDA to predict that the plan will fully address the violations reported under section 704(b). That is an unrealistic and highly subjective assessment. Further, this standard encourages manufacturers not to build check-and-change mechanisms into their correction plans for fear that FDA will regard these plans as inadequate because they do not guarantee corrections.

FDA can avoid these problematic results by accepting correction plans that provide a “reasonable assurance” that violations will be corrected. This standard draws from the reasonable-assurance assessment that FDA applies to premarket approval applications and, like that assessment, it recognizes that absolute certainty is an unworkable benchmark. In addition, FDA should clarify that a manufacturer may revise an accepted plan if the changes do not materially affect the plan’s correction of violations; it is inefficient for FDA and manufacturers to spend time vetting and agreeing upon minor modifications of correction plans.

There are related points that, in addition to the proper standard for correction plans, require clarification. These include how FDA will evaluate proposed correction plans and who will determine their acceptability. Likewise, the Draft CFG Guidance does not

\(^{12}\) FDARA section 704 (adding section (E)(i)(III) to 21 U.S.C. 381(e)(4))

\(^{13}\) Draft CFG Guidance, lines 156-157
state whether there will be supervisory review of acceptability decisions or how manufacturers may address decisions with which they disagree. Clearly, manufacturers may use section IV’s review process, but may they first, for example, meet with FDA staff to discuss their plans’ deficiencies and then resubmit them? Explanation of such points is essential to allow manufacturers to understand and effectively implement correction plans.

The Draft CFG Guidance also lacks basic instruction about how to submit correction plans. For example, the draft guidance directs the “owner, operator, or agent in charge of the establishment [to] submit a plan of correction in writing to the appropriate FDA office.” Such direction requires the manufacturer to rely more on luck than clear instruction in meetings FDA’s expectations. Which FDA office does the draft guidance mean: the ORA District Office that conducted the inspection? CDRH’s Office of Compliance? Some other FDA office? And to whom, specifically, should the manufacturer address the correspondence? To list just a few additional questions: Is there a deadline for submission of the plan of correction? May a manufacturer use its response to a form FDA 483 as a proposed correction plan? What is FDA’s review time? How will the Agency communicate its decision? Without anticipating and answering basic process questions, the draft guidance prevents manufacturers from knowing how to submit correction plans, how long FDA will take to review those plans, and how they will receive the Agency’s response. FDA must revise the draft guidance to fill such gaps.

Lastly, FDA must provide more information about the substantive summary that FDARA section 704 requires when FDA denies a CFG based on violations of 21 CFR 820. Simply repeating this requirement, the Draft CFG Guidance states that FDA will provide a “substantive summary of the specific grounds for noncompliance identified by FDA.” Missing is a discussion of what a “substantive summary” means. How does FDA define “substantive summary”? What are the summary’s contents? What does “noncompliance” mean (e.g., subject to an Official Action Indicated determination)? When will FDA provide the summary in relation to the CFG denial? How will the Agency provide the summary? What should a manufacturer do if it has questions about, or disagrees with, the summary? Here again, the draft guidance fails to provide fundamental information to effectuate Congress’s intent as expressed in FDARA section 704. As with the deficiencies noted above, FDA must revise the guidance to fill its gaps.

14 Draft CFG Guidance, lines 150-151
15 Draft CFG Guidance, lines 133-134
The Draft CFG Guidance’s process for reviewing CFG denials violates FDARA section 704.

FDARA section 704 directs FDA to “provide a process for a person who is denied a certification . . . to request a review that conforms to the standards of section 517A(b).” FDCA Section 517A(b) includes three clear requirements: (1) the right to request supervisory review within 30 days after an adverse decision; (2) an in-person or teleconference review, if so requested, within 30 days after the request; and (3) a decision on the matter not later than 45 days after the review is requested or within 30 days after an in-person meeting or teleconference.

The Draft CFG Guidance disregards these requirements. As a first step, it advises the “owner, operator, or agent in charge of the establishment” to request a review with CDRH’s Exports Branch. When this outreach is ineffective, the draft guidance directs establishments to CDRH’s review process, as articulated in the guidance, “Center for Devices and Radiological Health Appeals Processes: Guidance for Industry and Food and Drug Administration Staff.” Surprisingly, though, nowhere does the draft guidance meet Section 517A(b)’s three basic requirements: (1) there is no right to request supervisory review within 30 days after an adverse decision; (2) there is no provision for an in-person or teleconference review, if so requested, within 30 days after the request; and (3) there is no provision for a decision on the matter within 45 days after the review is requested or within 30 days after an in-person meeting or teleconference. To the contrary, the draft guidance specifically disclaims such requirements by asserting that CFG denials are not significant decisions.

The draft guidance’s disregard for these requirements violates the directive in FDARA section 704 for FDA to provide a review process that conforms to the standards of Section 517A(b). “Conform” means to “be similar or identical” or “to be in agreement or harmony.” One cannot credibly assert that the draft guidance is similar or identical to, or in agreement or harmony with, Section 517A(b) when it ignores that provision’s basic requirements. Nor does FDA cure this omission by claiming that CFG denials are not significant decisions. Neither FDARA section 704 nor Section 517A(b) requires FDA to decide whether CFG denials are significant decisions. Rather, section 704 requires a review process that conforms to the elements of Section 517A(b). Thus, CDRH could

16 FDARA section 704 (adding section (E)(ii)(I) to 21 U.S.C. 381(e)(4)) (emphasis added)
17 21 U.S.C. 360g-1, https://www.law.cornell.edu/uscode/text/21/360g-1
18 Inquiries about devices regulated by CBER should be directed to its Import and Export Staff. Draft CFG Guidance, lines 165-170
19 Draft CFG Guidance, lines 174-179
20 Draft CFG Guidance, lines 179-183.
easily treat CFGs as non-significant decisions and still provide requirements for a right of review, a meeting or teleconference when requested, and an agency decision within Section 517A(b)’s prescribed timeframes.

FDA must cure this violation of FDARA section 704. This means, at minimum, providing a review process for CFG denials that satisfies Section 517A(b)’s three basic requirements. And if FDA intends to frame the review process according to its Appeals Process guidance, then it should explicitly incorporate the additional review elements in that guidance.\textsuperscript{22}

**FDA must resolve inconsistencies within the current certification process.**

The Draft CFG Guidance acknowledges that a manufacturer sometimes may receive a CFG although “the device at issue was manufactured in an establishment that has received an FDA Inspectional Observations form (FDA form 483), issued under section 704(b) of the FD&C Act . . .”\textsuperscript{23} But FDA has failed to adjust other forms and procedures to reflect the availability of CFGs in these cases. For example, FDA’s warning letter boilerplate states, “Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.” That statement is no longer accurate, as manufacturers now may receive CFGs before violations have been corrected by agreeing with FDA on a plan to correct the violations. Likewise, manufacturers seeking CFGs now must attest that facilities involved in the manufacturing process operate in substantial compliance with 21 CFR 820. For a facility that receives an FDA form 483, even were the manufacturer to agree with FDA on a plan of correction, it could not truthfully attest that the facility complies with 21 CFR 820 until the corrections are complete.\textsuperscript{24} Thus, FDA must modify the CFG attestation, its warning letter boilerplate, and other agency forms and procedures to reflect that, in some cases, facilities with form 483 findings may receive CFGs.

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We note in closing that, in addition to its statutory and regulatory deficiencies, the Draft CFG Guidance reflects poor policy. In a time when the Presidential Administration is

\textsuperscript{22} E.g., Section 2.2’s discussion of the process for requesting a review, Section 2.5’s discussion of the request format, and Section 2.6’s discussion of the review conclusion

\textsuperscript{23} Draft CFG Guidance, lines 137-139

\textsuperscript{24} For another example of a document requiring correction, see CPGM 7382.845, \url{https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM244277.pdf} (“When violations meet the criteria for Situation I [an OAI inspection] . . . . Submit a copy of the Warning Letter to CDRH, Division of Risk Management Operations, Regulatory Policy and Systems Branch with a recommendation to rescind all current or unexpired certificates of export.”). Post FDARA section 704, in cases of agreed correction plans, rescission is improper.
promoting the sale of U.S. products abroad,\textsuperscript{25} FDA’s refusal to issue CFGs for products exported from outside this country materially impairs trade goals.\textsuperscript{26} More troubling, FDA’s policy prevents the export of products that the Agency deems safe and effective for U.S. citizens. Given Congress’s unequivocal statement that FDA should certify such exports, it is hard to imagine a rationale for the Agency’s refusal to do so.

We recognize that our comments and the specific ones that follow require substantial revision of the Draft CFG Guidance. We are available to assist FDA with this work however possible. Please do not hesitate to contact me at 202-434-7243 or ssilverman@advamed.org if you have any questions.

Respectfully Submitted,

/s/

Steve Silverman
Vice President
Technology & Regulatory Affairs
AdvaMed

Attachment

\textsuperscript{25} See. e.g., https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-promoting-free-fair-reciprocal-trade/ (“The President is also seeking new deals to open markets for U.S. exports and reshaping international institutions to serve the interests of U.S. workers.”)

\textsuperscript{26} To provide just one example, China will not permit importation of medical devices from U.S. companies unless they are accompanied by a CFG. The importance of the Chinese market for U.S. device manufacturers does not require explanation.
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<tr>
<td>1</td>
<td>Lines 124-125</td>
<td>Clarify that the prohibition against CFGs in cases of Class I and II recalls concerns general product recalls, but not lot-specific recalls. In addition, if the Class I or II recall remains open despite a request by the manufacturer for closure, provide a mechanism for timely closure of the recall.</td>
<td>We understand that safety and effectiveness concerns may prevent CFGs in cases of general Class I and II recalls. But where a manufacturer can identify the specific lots affected by the cause of a Class I or II recall, then the remaining lots should be eligible for CFGs. Because these lots are unaffected by the cause of the recall, their safety and effectiveness is not at risk, and FDA should issue CFGs for them when other prerequisites are satisfied. In addition, there may be cases in which a manufacturer has requested closure of a Class I or II recall and then seeks a CFG for devices to be exported from facilities involved in the recall. In these cases, where a closure request is pending, the manufacturer should not be penalized by sometimes long delays in FDA’s closure decision. Instead, the Agency should provide a mechanism for prompt closure decisions and, following closure, issuance of CFGs.</td>
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<td>2</td>
<td>Lines 126-127</td>
<td>Clarify that “out of compliance” means an Official Action Indicated (OAI) determination following an FDA inspection.</td>
<td>FDA has explained to AdvaMed that it withholds CFGs based only on OAI determinations following Agency inspections, and that a Voluntary Action Indicated determination (which still may involve deviations recorded on a form FDA 483) will not preclude issuance of a CFG. FDA should make this point explicitly.</td>
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<td>3</td>
<td>Lines 145</td>
<td>Add, “In determining whether there is an agreed plan of correction following an FDA-recognized audit, FDA will use the same mechanism as the one used for a plan of correction following an FDA inspection.”</td>
<td>FDA should clarify that it will use the same evaluative mechanism for plans of corrections following FDA inspections and plans of correction following FDA-recognized audits.</td>
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<td>4 Lines 155-157</td>
<td>Revise to, “The FDA will review the plan and, within 15 calendar days, notify via email the owner, operator, or agent on behalf of the owner or operator whether the plan is sufficient to address the violations documented in the inspectional observations. If FDA does not respond within 15 calendar days of receipt of the plan, then the plan will be considered agreed to by FDA. If the plan is agreed to, then FDA will issue a CFG. If FDA denies the plan, then within 30 calendar days of receipt of the plan, FDA will provide in writing to the owner, operator, or agent on behalf of the owner or operator an explanation of the denial and the findings upon which the denial is based. The owner, operator, or agent on behalf of the owner or operator may follow the process described in this guidance to request a review of the denial.”</td>
<td>This revision resolves some of the deficiencies discussed in our cover letter relating to the mechanism that FDA will use to receive and evaluate proposed plans of correction. Note that these revisions are a partial solution and that, as our cover letter states, this part of the Draft CFG Guidance requires substantial additional revision. The revision of “agent in charge of the establishment” to “agent on behalf of the owner or operator” clarifies that the owner or operator of an establishment may designate an agent who is a party other than the agent in charge of the establishment.</td>
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<td>5 Line 2 161-162</td>
<td>Revise to, “A person who has been denied a CFG may at any time request a review of the denial, including a review to present new information relating to actions taken by such person to address the reasons identified by [FDA]. . . .”</td>
<td>21 U.S.C. 801(e)(4)(E)(ii)(I), as added by FDARA section 704, entitles those denied a CFG to a review that conforms with 21 U.S.C. 360g-1(b), which states that “Any person may request a supervisory review of the significant decision . . . .” This supervisory review is not predicated on the production of new evidence. So, while FDARA section 704 permits submission of new evidence at any time (“Notwithstanding any previous review . . . a person who has been denied a certification . . . may at any time request a review in order to present new information . . . .” FDARA 704(1)), FDA may not predicate a review request on the submission of new information.</td>
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<td>6 Line 170</td>
<td>Add, “In requesting a review, the owner, operator, or agent on the owner’s or operator’s behalf need not submit documentation previously submitted to the Agency, e.g., documentation in response to FDA form 483 observations.”</td>
<td>This revision clarifies that parties seeking review may reference, but need not re-submit, inspection or audit-related documentation previously submitted to FDA. Such a re-submission would be redundant and inefficient.</td>
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