Section 3308 of The Food and Drug Omnibus Reform Act of 2022 (FDORA) enacted as part of the Consolidated Appropriations Act, 2023 (December 29, 2022) amended section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of FDORA, and certain sections of this guidance may no longer be current as a result. As amended, section 517A(a)(1) no longer includes Breakthrough Device Designation Requests. For more information, please contact the CDRH Ombudsman at CDRHOmbudsman@fda.hhs.gov .

Contains Nonbinding Recommendations

Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A

Guidance for Industry and Food and Drug Administration Staff

Document issued on March 27, 2020.

Document originally issued on July 30, 2014

As of March 27, 2020, this document supersedes "Center for Devices and Radiological Health Appeals Processes: Questions and Answers about 517A – Guidance for Industry and Food and Drug Administration Staff" issued on August 1, 2019.

For questions about this document, contact the CDRH Ombudsman at 301-796-5699 or CDRHOmbudsman@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

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Identify all comments with the docket number FDA-2013-D-0501. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document provides the Center for Devices and Radiological Health (CDRH or the Center) interpretation of key provisions set forth in section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[1] as those provisions pertain to requests for appeals of significant decisions under 21 CFR 10.75, as well as for the timeframes and procedures of regulatory decisions and actions taken by CDRH under 21 CFR 800.75.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Section 517A of the FD&C Act contains provisions for the documentation and review of certain decisions in the premarket review of device submissions. Specifically, this provision states:

[1] Section 517A of the FD&C Act was added by section 603 of the FDA Safety and Innovation Act (FDASIA) of 2012, and subsequently amended by sections 3051 and 3058 of the 21st Century Cures Act of 2016.

> (a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, a request for designation under section 515B[2], or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.
> (2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such substantive summary to the person who is seeking to submit, or who has submitted, such report or application.
> (3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS. — The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.
> (b) REVIEW OF SIGNIFICANT DECISIONS.—
> (1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.
> (2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.
> (3) TIMEFRAME.—
> (A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.
> (B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.

21 CFR 10.75 was amended to add paragraph (e) to require that requests for internal agency supervisory review of a decision within CDRH also comply with § 800.75 (21 CFR 800.75). This change to the regulations encompasses both significant decisions under section 517A of the FD&C Act and other decisions by CDRH employees for which review is requested through the supervisory chain within CDRH. Further, 21 CFR 800.75 includes timeframes for industry for decisions made by CDRH that are outside the scope of section 517A of the FD&C Act.

CDRH has developed this guidance document as a companion to Center for Devices and

[2] Section 3051 of the Cures Act, "Breakthrough Devices" added section 515B of the FD&C Act, as amended by section 901(f)(2) of the FDA Reauthorization Act of 2017 (Public Law 115-52).

Radiological Health Appeals Processes – Guidance for Industry, Stakeholders, and Food and Drug Administration Staff [3] to provide further clarity of several provisions of the law and regulations.

III. Questions about Section 517A

A. What is a "Significant Decision"?

The documentation and review procedures required by section 517A of the FD&C Act apply only to "significant decisions" concerning submissions under sections 510(k) (Premarket Notification), 515 (Premarket Approval or "PMA"/Humanitarian Device Exemption or "HDE"), 515B (Breakthrough Devices), or 520(g) (Investigational Device Exemption or "IDE") of the FD&C Act. "Significant decision" is not explicitly defined in section 517A of the FD&C Act. For purposes of this guidance, we refer to "significant decisions" made by CDRH that are within the scope of section 517A as "517A decisions." Therefore, a request for supervisory review of a 517A decision must follow the procedures and timeframes set forth in section 517A(b) of the FD&C Act and its implementing regulations found in 21 CFR 800.75. As stated in 21 CFR 800.75, 517A decisions include the following types of decisions:

- 510(k) (Premarket Notification): Not Substantially Equivalent; Substantially Equivalent;
- PMA/HDE (Premarket Approval/Humanitarian Device Exemption): Not Approvable; Approvable; Approval; Denial;
- Breakthrough Device Designation Request[4]: Request for breakthrough designation for devices subject to 510(k), PMA, or De Novo classification. Grant; Denial of request for breakthrough designation;
- IDE (Investigational Device Exemption): Disapproval; Approval;
- Failure to Reach Agreement on a Protocol under Section 520(g)(7) of the FD&C Act; and
- "Clinical Hold" Determinations under Section 520(g)(8) of the FD&C Act.

Under 21 CFR 800.75, the timeframes and procedures specified in section 517A of the FD&C Act for 517A decisions regarding premarket submissions apply to sequential requests for supervisory review of such decisions within CDRH. For example, if a company that requests supervisory review of a 517A decision at the Office level further appeals the Office decision to the next higher level, FDA would apply the procedures and timeframes specified in section 517A of the FD&C Act to both of these appeals.

There are regulatory actions that do not constitute 517A decisions for purposes of 21 CFR

[3] Center for Devices and Radiological Health Appeals Processes – Guidance for Industry and Food and Drug Administration Staff, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.

[4] Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.

800.75 and thus are not subject to 21 CFR 800.75(b)(1). These types of appeals are subject to 21 CFR 10.75 and 21 CFR 800.75(b)(2). CDRH refers to these decisions as "non-517A decisions". Examples of non-517A decisions include, but are not limited to, the following:

- 510(k) Requests for Additional Information;
- De Novo Requests for Additional Information and Final Decisions;
- PMA Major Deficiency Letters;
- 510(k), PMA and HDE Refuse to Accept/Refuse to File Letters;
- Postmarket Surveillance Orders under Section 522 of the FD&C Act;
- Clinical Laboratory Improvement Amendments (CLIA) Waiver Decisions;
- Warning Letters; and
- Response Letter to a Request for Information under Section 513(g) of the FD&C Act.

These requests for supervisory review would not trigger the requirements under section 517A of the FD&C Act.

Note that the requirements for non-517A decisions within 21 CFR 10.75 and 21 CFR 800.75(b)(2) also apply to sequential requests for supervisory review of such decisions within CDRH. As such, a request for supervisory review within CDRH under 21 CFR 10.75 for a non-517A decision that is not received by CDRH within 60 days after the date of the decision involved will be denied as untimely, unless CDRH, for good cause related to circumstances beyond the control of the submitter, such as snow emergency, Federal Government shutdown, or other unforeseen emergency event, permits the request to be filed after 60 days[5].

B. What is a "substantive summary"?

Section 517A of the FD&C Act requires the Center to provide, upon request of a person who is seeking to submit or who has submitted a 510(k), PMA, IDE, HDE, or Breakthrough Designation Request, a "substantive summary" of the scientific and regulatory rationale for any 517A decision regarding such submission, including documentation of how the least burdensome requirements were considered and applied, and documentation of significant controversies or differences of opinion and the resolution thereof. For example, when the submitter of a Premarket Notification under section 510(k) of the FD&C Act receives a Substantially Equivalent or Not Substantially Equivalent decision from CDRH, the submitter may then request, and CDRH must provide, a "substantive summary" of the rationale for the decision.

For decisions that are subject to this provision, the "substantive summary" may be the final version of the review memorandum by the lead reviewer or another summary document that includes the following elements:

- An explanation of the rationale for the regulatory decision;

[5] 21 CFR 800.75(b)(2)

- An explanation regarding how the least burdensome requirements were considered and applied consistent with sections 513(i)(1)(D), 513(a)(3)(D), and 515(c)(5) of the FD&C Act.
- Documentation of significant controversies or differences of opinion, i.e., ones the resolution of which had a direct bearing on the regulatory decision; and
- References to published literature and consensus standards upon which the decision-maker relied.

C. Who may request documentation of 517A decisions under section 517A of the FD&C Act, and how does this provision relate to requests under the Freedom of Information Act (FOIA)?

FDA interprets section 517A(a)(2) of the FD&C Act to permit persons who have submitted or who are seeking to submit 510(k)s, PMAs, IDEs, HDEs, or a Breakthrough Designation Request to request substantive summaries of 517A decisions regarding their own device (not the devices of others) without having to file a request under FOIA. For example, a sponsor, who has received a decision for an IDE, may request a substantive summary of a decision.

Since FDA will only be providing these summaries to the owner of any proprietary information contained therein, generally there should not be any need to withhold trade secret or confidential commercial information (CCI) or any other information in the summary. If someone other than the owner of a device wishes to obtain a substantive summary of a 517A decision regarding such device, that person would need to file a FOIA request. Trade secret and CCI would be withheld in FDA's response to such a FOIA request, but there would be no information exempt from disclosure under 5 U.S.C. § 552(b)(5).

D. How to request a substantive summary under section 517A of the FD&C Act?

A request for substantive summary under 517A(a)(2) of the FD&C Act should be made by submitting the request via the processes established for premarket submissions to CDRH's Document Control Center.[6] The request should clearly be identified as a request for substantive summary under 517A, including by prominently stating "Request for Substantive Summary under 517A" at the top of the request, and should clearly identify the associated identifying number for the relevant premarket submission (e.g., 510(k) submission number).

[6] See the guidance "eCopy Program for Medical Device Submissions" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions).