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

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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

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Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1 Introduction

This draft guidance document provides the Center for Devices and Radiological Health (CDRH or the Center) proposed interpretation of key provisions of Section 517A of the Food, Drug and Cosmetic Act (FD&C Act), which was added by section 603 of the FDA Safety and Innovation Act (FDASIA) of 2012, as those provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH.

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 guidances means that something is suggested or recommended, but not required.

2 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:

> (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, 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.
> (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.

We have added the clear timeframes for the processing of appeals of significant decisions in section 517A(b)(2) and (3) to the final version of *Center for Devices and Radiological Health Appeals Processes;Guidance for Industry and Food and Drug Administration Staff* (2013) (Appeals Guidance). (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/u

cm284651.htm) Other terms in section 517A, however, require interpretation. CDRH has developed this draft guidance document as a companion to the Appeals Guidance to provide proposed interpretations of several provisions of the new law. When finalized, CDRH intends to include the questions and answers in this draft guidance as an appendix to the Appeals Guidance.

3 Questions about Section 517A

3.1 What is a "Significant Decision"?

The documentation and review procedures required by section 517A apply only to "significant decisions" concerning submissions under sections 510(k) (Premarket Notification), 515 (Premarket Approval or "PMA"/Humanitarian Device Exemption or "HDE") or 520(g) (Investigational Device Exemption or "IDE"). "Significant decision" is not defined. To ensure the enhanced procedural protections and timelines for actions by both CDRH and device applicants are applied to important decisions at the final stage of review, while permitting additional flexibility in decision-making earlier in the review process, CDRH believes the term should include the following:

- 510(k): Not Substantially Equivalent; Substantially Equivalent
- PMA/HDE: Not Approvable; Approvable with Conditions; Approval
- IDE: Disapproval; Approval
- Failure to reach agreement on a protocol under section 520(g)(7)

On the other hand, CDRH does not believe that actions earlier in the review process constitute "significant decisions." Thus, refusals to accept/file, requests for additional information, and deficiency letters during the review of a premarket submission would not trigger the requirements under section 517A.

CDRH intends that the time frames and procedures specified in section 517A for significant decisions regarding premarket submissions will apply to all requests for supervisory review of such decisions within the Center. For example, a company may request supervisory review by an Office Director of a Not Substantially Equivalent decision issued by a Division Director, and then appeal the Office Director's decision to the Center Director. FDA intends to apply the procedures and timeframes specified in section 517A to both of these appeals.

3.2 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, or HDE, a "substantive summary" of the scientific and regulatory rationale for any significant decision regarding such submission, including 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) 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;
- 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.

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

FDA interprets section 517A(a)(2) to permit persons who have submitted or who are seeking to submit 510(k)s, PMAs, IDEs, or HDEs to request substantive summaries of significant decisions regarding their own device (not the devices of others) without having to file a request under the FOIA. For example, a sponsor seeking to submit an IDE may request a substantive summary of a decision on a binding protocol agreement under section 520(g)(7) pertaining to a study of its device.

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 (generally the device sponsor or manufacturer) wishes to obtain a substantive summary of a significant decision regarding such device, that person would need to file a FOIA request. Generally, trade secret and CCI would have to 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).