The 21st Century Cures Act (Cures), signed into law on December 13, 2016, amended several sections of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of Cures, and certain sections of this guidance may no longer be current as a result. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information please contact CDRH-Cures@fda.hhs.gov.

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

Guidance for Industry and Food and Drug Administration Staff

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For questions regarding this document, contact the Office of the Center Director at 301-796-5900 or contact Ruth Fischer at 301-796-5735 or by electronic mail at ruth.fischer@fda.hhs.gov .

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

Office of the Center Director

Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 guidance document provides the Center for Devices and Radiological Health (CDRH or the Center) 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.

The statutory timeframes for the processing of appeals of significant decisions under section 517A(b)(2) and (3) of the FD&C Act are discussed in a separate guidance, *Center for Devices and Radiological Health (CDRH) Appeals Processes: Guidance for Industry and Food and Drug Administration Staff* (May 17, 2013) (Appeals Guidance). (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm). Other terms in section 517A of the FD&C Act, however, require

interpretation. CDRH has developed this guidance document as a companion to the Appeals Guidance to provide interpretations of several provisions of the new law.

3 Questions about Section 517A

3.1 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") or 520(g) (Investigational Device Exemption or "IDE") of the FD&C Act. "Significant decision" is not defined. For purposes of this guidance, we refer to "significant decisions" as "517A decisions." 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 517A decisions should include the following:

- 510(k): Not Substantially Equivalent; Substantially Equivalent
- PMA/HDE: Not Approvable; Approvable; Approval; Denial
- IDE: Disapproval; Approval
- Failure to Reach Agreement on a Protocol under Section 520(g)(7) of the FD&C Act
- "Clinical Hold" Determinations under Section 520(g)(8) of the FD&C Act

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

On the other hand, there are regulatory actions that do not constitute 517A decisions, but which remain subject to review under 21 CFR 10.75. CDRH refers to these decisions as "non-517A" decisions. Examples of a request for supervisory review which may be made under 21 CFR 10.75 for non-517A decisions include, but are not limited to, the following:

- 510(k) Requests for Additional Information
- PMA Major Deficiency Letter
- 510(k) and PMA Refuse to Accept Letters

- Postmarket Surveillance Orders under Section 522 of the FD&C Act
- CLIA Waiver Decisions
- Warning Letters
- 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.

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 517A 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) 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;
- 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 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, or HDEs to request substantive summaries of 517A 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 520(g)(7) of the FD&C Act 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 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).