4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0501]

Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A; Guidance for Industry and Food and Drug Administration Staff

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A." This document provides CDRH's interpretation of key provisions of section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which were added by the FDA Safety and Innovation Act (FDASIA), as these provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single copy of the guidance document entitled "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A" to the Office of the Center Director,

Guidance and Policy Development, CDRH, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ruth Fischer, CDRH, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5400, Silver Spring, MD 20993-0002, 301-796-5735.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, section 517A of the FD&C Act (21 U.S.C. 360g-l) was added by section 603 of FDASIA (Pub. L. 112-114). CDRH developed this guidance as a companion document to the final guidance entitled "Center for Devices and Radiological Health Appeals Processes," which was issued on May 17, 2013. The guidance "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A" provides CDRH's interpretation of key provisions of section 517A of the FD&C Act as these provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH. In particular, this document provides interpretations surrounding the statutory terms "significant decision" and "substantive summary." It also addresses who may

request documentation of significant decisions under section 517A of the FD&C Act, and how this provision relates to requests under the Freedom of Information Act.

In the Federal Register of May 17, 2013 (78 FR 29140), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by August 15, 2013. FDA considered the public comments received and revised the guidance, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on Center for Devices and Radiological Health's Appeals Processes: Questions and Answers About 517A. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A," may send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1821 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332. The collections of information in the guidance document "Center for Devices and Radiological Health Appeals Processes" have been approved under OMB control number 0910-0738.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: July 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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