4160-01-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Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A." This draft document provides CDRH's proposed interpretation of key provisions of the Federal Food Drug and Cosmetic Act (FD&C Act), which were added by the FDA Safety and Innovation Act (FDASIA), 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. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About

517A" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: David S. Buckles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G470, Silver Spring, MD 20993-0002, 301-796-5447.

I. Background

In July of 2012, section 517A of the FD&C Act (21 U.S.C. 360g-1) was added by section 603 of FDASIA (Public Law 112-114). CDRH developed this draft guidance as a companion document to the guidance entitled "Center for Devices and Radiological Health Appeals Processes," (Appeals Guidance) which is also announced in this issue of the Federal Register, to provide proposed interpretations of the new law. This document provides interpretations of the terms "significant decisions" 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. When this guidance is

finalized, CDRH intends to include the questions and answers in this draft guidance as an appendix to the Appeals Guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on CDRH's appeals processes. 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 draft guidance may do so by using 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.

To receive "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A" you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1821 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that 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 the guidance document "Center for Devices and Radiological Health Appeals Processes" are approved under OMB control number 0910-0738 (expires April 30, 2016). The draft guidance also refers to currently approved

information collections found in FDA regulations. The collections of information in 21 CFR part 807 subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 are approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814 subpart H are approved under OMB control number 0910-0332.

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: May 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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