4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0893]

Center for Devices and Radiological Health Appeals Processes; Guidance for Industry and FDA Staff; Availability

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." This document describes the processes available to outside stakeholders to request additional review of decisions or actions by CDRH employees which include requests for supervisory review of an action, petitions, and hearings. Of these, the most commonly used process is the request for supervisory review (a "10.75 appeal"). This document provides general information about each process as well as guidance on how to submit related requests to CDRH and FDA.

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: Submit written requests for single copies of the guidance document entitled "Center for Devices and Radiological Health Appeals Processes" 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 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.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance supersedes two previous guidance documents: "Medical Device Appeals and Complaints: Guidance for Dispute Resolution," dated February 1998 and "Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA," dated July 2001.

In the Federal Register of December 28, 2011 (76 FR 81511), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by April 26, 2012. In July 2012, section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360g-1) was added by section 603 of the FDA Safety and Innovation Act (FDASIA) (Public Law 112-114). FDA considered the public comments received and revised the guidance, as appropriate, and in accordance with the new requirements established by section 603 of FDASIA.

Section 517A includes new requirements pertaining to the process and timelines for appeals, made under 21 CFR 10.75 (10.75 appeal) of "significant decisions" regarding 510(k) premarket notifications, applications for premarket approval (PMAs), and applications for investigational device exemptions (IDEs). In this guidance document, the term "significant decision" refers to significant decisions pertaining to these submissions.

Elsewhere in this issue of the Federal Register, FDA is announcing the Agency's proposed interpretation of this provision (for example, what constitutes a "significant decision") in a draft guidance document entitled "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A."

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 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 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" 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 1742 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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. The guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR 10.30, 21 CFR 10.33, and 21 CFR 10.35 are approved under OMB control number 0910-0183; the collections of information in 21 CFR part 12 are approved under OMB control number 0910-0184; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910-0309.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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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