

(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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 15, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A" to the Division of Small Manufacturers,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Submit electronic comments on the draft guidance to 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 (Pub. L. 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 CDRH developed this draft guidance as a companion document to the guidance entitled "Center for Devices and Radiological Health Appeals Processes," (Appeals Guidance) which is also announced in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](mailto: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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## 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) (Pub. L. 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](mailto: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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anesthetic and Analgesic Drug Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA’s regulatory issues.

*Date and Time:* The meeting will be held on July 17, 2013, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-