4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes." This document describes the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. The document also provides general information about each process as well as guidance on how to submit related requests to CDRH and FDA. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes" to the Division of Small Manufacturers, International, and Consumer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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance for industry and FDA staff entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes" revises, updates, and combines two previous guidance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. When finalized, "Center for

Devices and Radiological Health (CDRH) Appeals Processes" is intended to supersede the previously listed two guidance documents.

The draft document is intended to provide clarity to internal and external audiences regarding CDRH's appeal processes. Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. In most cases, it is up to the party seeking resolution of an adverse action or resolution of a difference of opinion to determine the appropriate process for a given circumstance or issue. The guidance describes these mechanisms and includes the following topics: (1) Appealable actions (i.e., warning letters, post-approval study requirements, premarket decisions, deficiency letters, or requests for additional information); (2) paths and options available at different stages of appeals; (3) use of expedited or "paper" appeals versus appeal meetings or teleconferences; (4) recommended format for appeals; (5) appeal authorities; (6) appeal conflicts; and (7) issues that are appropriate for dispute resolution.

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 (CDRH) 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes

This draft guidance is intended to describe the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. There are several processes for resolution, including a request for supervisory review of an action, petitions, and hearings. The proposed information collection seeks approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees under this guidance. The draft guidance also refers to currently approved information collections found in FDA regulations.

The collections of information in 21 CFR 10.30 are approved under OMB control number 0910-0437; the collections of information in 21 CFR 10.33 are approved under OMB control number 0910-0485; the collections of information in 21 CFR 10.35 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part 12 are approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910-0309.

Description of Respondents: The respondents to this collection of information are manufacturers, applicants, sponsors, or any other interested persons requesting additional review of decisions and actions taken by CDRH employees. The Agency estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Guidance Title	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Center for Devices and Radiological Health (CDRH) Appeals Processes	50	1	50	8	400
[1] There are no capital costs or operating and maintenance costs associated with this collection of information.					

FDA estimates it will receive 50 requests annually from outside stakeholders requesting additional review of decisions and actions by CDRH employees. The Agency reached this estimate based on data collected about requests received over the last 2 years. FDA estimates it will take outside stakeholders approximately 8 hours to prepare a request based on the Agency's experience with past requests.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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