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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes--(OMB Control Number 0910-NEW)

The 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.

The 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.

This 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 guidance also refers to currently approved information collections found in FDA regulations.

The collections of information in 21 CFR 10.30, 10.33, and 10.35 have been approved under OMB control number 0910-0183; the collections of information in 21 CFR part 12 have been approved under OMB control number 0910-0184; the collections of information for 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information under 21 CFR part 814 have been approved under 0910-0231; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910-0309.

In the Federal Register of December 28, 2011 (76 FR 81511), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 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.

FDA 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
CDRH Appeals Processes Guidance Document	50	1	50	8	400
Total	50	1	50	8	400

[1]There are no capital costs or operating and maintenance costs associate with this collection of information.

Dated: February 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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