4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0145]

Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I." The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), requires FDA to establish and publish criteria to reaccredit or deny reaccreditation to persons accredited by FDA under the FD&C Act to perform premarket review of medical devices. This draft guidance describes the accreditation, reaccreditation, and accreditation withdrawal processes, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to third party reviewers under the Third Party Review Program. The criteria will facilitate international harmonization and, thereby, in the future, allow us to leverage resources with those of regulating bodies in other countries. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I" to the Division of Small Manufacturers,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Submit electronic comments on the draft guidance to http://www.regulations.gov.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 FD&C Act, as amended by FDASIA, requires FDA to establish and publish criteria to reaccredit and deny reaccreditation to third parties accredited under section 523 of the FD&C Act (21 U.S.C. 360m) to perform premarket review of class I and eligible class II premarket notification (510(k)) submissions. This draft guidance describes the accreditation, reaccreditation, and accreditation withdrawal processes, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to firms under the Third Party Review Program (TPRP).

The International Medical Device Regulators Forum (IMDRF) recently issued a proposed draft document entitled "Recognition Criteria for Medical Device Auditing Organizations" (IMDRF document), available at www.imdrf.org/docs/imdrf/final/consultations/imdrf-mdsap-criteria.pdf. The IMDRF was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world, which includes FDA, who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization and convergence (see http://www.imdrf.org).

The IMDRF draft document reflects the group's effort to develop the foundations for a Single Audit Program for medical devices that includes criteria for the recognition and rerecognition of third party auditing organizations. (The IMDRF document refers to the "recognition" of third parties, whereas the FD&C Act refers to the "accreditation" of third parties.) The IMDRF document includes criteria used or proposed by member countries for

conformity assessment bodies and third party reviewers. The IMDRF also plans to incorporate specific requirements for competency and considerations for codes of conduct that together will constitute the basis for the recognition of third party auditors under a Single Audit Program. When finalized and adopted, this document will represent a harmonized standard for participating countries and could be useful to FDA to the extent consistent with the FD&C Act and other relevant laws and regulations.

In an effort to develop accreditation and reaccreditation criteria that could be used in the future for a harmonized TPRP, in this draft guidance we use recognition criteria described in the IMDRF document as part of the criteria for third party accreditation by FDA. We intend to incorporate information from the IMDRF document in a subsequent draft guidance to the extent appropriate as part of the criteria for accreditation and reaccreditation of reviewers under the TPRP.

We plan to update and re-issue this guidance in draft again for further comment once the IMDRF has finalized the IMDRF document, which is expected to be in December 2013. This guidance does not address accreditation of inspectors under the FDA Third Party Inspection Program.

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 the accreditation and reaccreditation process for firms under the TPRP. 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 "Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I," 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 1815 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. 3501-3502), 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 this 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.

Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I: Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance describes revised accreditation, new reaccreditation, and accreditation withdrawal processes, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to third party reviewers under the TPRP. The guidance provides recommendations regarding the information that should be submitted for consideration to accredit and reaccredit. This guidance when finalized, will revise the collections of information for FDA's Third Party Review Program, OMB control number 0910-0375.

FDA estimates the burden of this collection of information as follows:

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

Submission of Information for Accreditation Program	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Requests for accreditation (current requirement)	1	1	1	24	24
Requests for reaccreditation (proposed requirement)	4	1	4	24	96
510(k) reviews conducted by accredited third	10	26	260	40	10,400

parties (current requirement)					
Total					10,520

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

Retention of Information for Reaccreditation Program	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510(k) reviews (current requirements)	10	26	260	10	2,600
Reaccreditation documentation	10	1	10	10	100
Total					2,700

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

Currently approved collection requirements:

1. Reporting

    a. Requests for accreditation: In the past 3 years, the Agency has averaged receipt of one application for accreditation for third party review.

    b. Premarket notification (510(k)) reviews conducted by accredited third parties: According to FDA's data in 2009, the Agency has experienced that the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

2. Recordkeeping

    a. Third party reviewers are required to keep records of their review of each submission. According to FDA's in 2009, the Agency anticipates approximately 260 submissions of 510(k)s for third party review per year.

Proposed revisions to currently approved collection:

1. Reporting

a. Requests for reaccreditation: The Agency anticipates an average receipt of four applications for reaccreditation for third party review.

2. Record retention

a. Record retention related to reaccreditation program: The Agency anticipates that there will be a requirement to retain documentation to support reaccreditation.

The respondents for this information collection are private sector, for-profit firms seeking accreditation and reaccreditation to participate as third party reviewers to review 510(k)s for certain low-to-moderate risk devices. FDA estimates that it will receive approximately four requests for reaccreditation annually. The Agency reached this estimate by reviewing the number of existing accredited firms under the TPRP program and prorating the reaccreditation of each firm every 3 years.

FDA estimates from past experiences involving the accreditation and TPRP processes that requests will take approximately 24 hours per respondent. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for accreditation and reaccreditation under the TPRP. FDA requests comments on these estimates and the methodology used to estimate the burdens.

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 necessary to send only 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: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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