4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2565]

510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "510(k) Third Party Review Program." This draft guidance provides a comprehensive look into FDA's current thinking regarding the 510(k) Third Party (TP) Review Program authorized under section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In an effort to encourage harmonization, this guidance proposes to refer to, for the purpose of the TP Review Program, where appropriate and consistent with the FD&C Act and other applicable laws and regulations, the elements from the International Medical Device Regulators Forum's regulatory assessment program called the Medical Device Single Audit Program. In addition, the Food and Drug Administration Safety and Innovation Act (FDASIA) requires FDA to establish and publish in the **Federal Register** criteria to reaccredit and deny reaccreditation of TP Review Organizations. Those criteria, including others, are described in this draft guidance. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Submit written or electronic comments on the collection of information by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES:

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-2565 for the draft guidance entitled "510(k) Third Party Review Program." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

"confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "510(k) Third Party (TP) Review Program" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Stacy Cho, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5625, Silver Spring, MD 20993, 240-402-6158.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the TP Review Program is to implement section 523 of the FD&C Act (21 U.S.C. 360m). Section 523 authorizes FDA to accredit third parties to review premarket notification (510(k)) submissions and recommend the initial classification of certain devices. FDA's implementation of section 523 includes establishing a process of recognition of qualified third parties to conduct the initial review of 510(k) submissions for certain low-to-moderate risk devices eligible under the TP Review Program (formerly known as the Accredited Persons Program). The TP Review Program is intended to allow review of such devices by TP Review Organizations in order to provide manufacturers of these devices an alternative review process that may yield more rapid 510(k) decisions. TP Review Organizations conduct the equivalent of an FDA premarket review of a 510(k) submission, and then forward their reviews, recommendations, and 510(k) submissions to FDA for a decision concerning the substantial equivalence of a device.

In February 2011, the International Medical Device Regulators Forum (IMDRF) was conceived to discuss future directions in medical device regulatory harmonization. The IMDRF is a voluntary group of medical device regulators from around the world, including representatives from the 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.

As one of its initial actions, the IMDRF developed the regulatory assessment program called the Medical Device Single Audit Program (MDSAP), which is outlined in a collection of documents (Ref. 1). The IMDRF MDSAP documents provide the fundamental building blocks

of an auditing program by providing a common set of criteria to be utilized for the recognition and monitoring of entities that perform regulatory audits and other related functions.

In an effort to encourage harmonization, this draft guidance refers to the standards described in the IMDRF MDSAP documents as criteria FDA will consider for recognition, rerecognition, recognition denial, rerecognition denial, and recognition withdrawal of TP Review Organizations under the TP Review Program. In addition, the draft guidance does not use those statutory terms found under section 523 of the FD&C Act such as accredited persons, accredit, or reaccredit, but defines such terms as third party review organizations, recognition, and rerecognition as synonymous terms. FDA appreciates the advantages of harmonized international standards, and FDA believes that, when finalized, this guidance document will help to further bring the TP Review Program into harmony with such standards, as well as provide clarity and consistency for industry.

In addition, the goal of this draft guidance is to provide FDA's current thinking on the TP Review Program in the following areas: (1) TP Review Organizations review of 510(k) submissions; (2) requirements and recommendations for recognition and rerecognition of TP Review Organizations under the TP Review Program; (3) content and format of a TP Review Organization's application for initial recognition and rerecognition; and (4) suspension or withdrawal of recognition. Further, section 611 of FDASIA (Pub. L. 112-144) requires FDA to establish and publish in the **Federal Register** criteria to reaccredit and deny reaccreditation of TP Review Organizations. Those criteria are described in this draft guidance and if finalized, the guidance will represent FDA's implementation of section 611 of FDASIA.

Upon issuance, this draft guidance will replace the draft guidance entitled "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" issued on February 15, 2013 (Ref. 2).

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 represents the current thinking of FDA on the "510(k) Third Party Review Program." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes 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 the draft guidance entitled "510(k) Third Party Review Program," you may either send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500013 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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 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.

Medical Devices; Third-Party Review Under FDAMA

OMB Control Number 0910-0375--Revision

This draft guidance describes the recognition, rerecognition, recognition/rerecognition denial, and recognition withdrawal processes, including criteria that will be considered for such processes under the TP Review Program. The draft guidance provides how TP Review Organizations can apply for recognition and rerecognition, as well as describes the information to be kept, maintained, and submitted to FDA for the purpose of TP review. The guidance, when finalized, will revise the collections of information for FDA's Third Party Review Program, OMB control 0910-0375. For clarity, we also propose to revise the title of the information collection to "Third Party Review Program for Medical Device Premarket Notification." Additionally, to be consistent with the guidance, we propose to revise OMB control number

0910-0375 to use the terms recognition, rerecognition, recognition/rerecognition denial, and recognition withdrawal to refer to the process of accreditation, reaccreditation, accreditation/reaccreditation denial, and withdrawal of accreditation under section 523 of the FD&C Act.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for recognition (current approval)	1	1	1	24	24
Requests for rerecognition (proposed)	4	1	4	24	96
510(k) reviews conducted by recognized third party review organizations (current approval)	10	26	260	40	10,400
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]

	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510(k) reviews (current approval)	10	26	260	10	2,600
Recognition/Rerecognition documentation (proposed)	10	1	10	10	100
Total					2700

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

FDA estimates from past experiences regarding the recognition and rerecognition processes that the application will take approximately 24 hours per respondent. This average is based upon estimates by FDA administrative and technical staff that are familiar with the recognition and rerecognition processes under the TP Review Program. FDA requests comments on these estimates and the methodology used to estimate the burdens.

Currently approved information collection:

- Reporting

- Requests for recognition: In the past 3 years, the Agency has averaged receipt of 1 application for recognition for third party 510(k) review.
- 510(k) reviews conducted by recognized TP Review Organizations: According to FDA's data in 2009, the number of 510(k)s submitted for third party review is approximately 260 annually, which is on average 26 annual 510(k) reviews per each of the 10 recognized TP Review Organizations.

- Recordkeeping
  - TP Review Organizations are expected to keep and maintain records related to their review of 510(k) submissions. According to 2009 data, the Agency anticipates approximately 260 submissions of 510(k)s for third party review per year.

Proposed revisions to the currently approved information collection:

- Reporting
  - Requests for rerecognition: The Agency anticipates an average annual receipt of four applications for rerecognition for third party 510(k) review. The Agency reached this estimate by reviewing the number of existing recognized firms under the TP Review Program and anticipating the number of firms applying for rerecognition every 3 years.
- Recordkeeping
  - The Agency expects TP Review Organizations to retain and maintain documentation related to recognition and rerecognition.

The respondents for this information collection are private sector, for-profit firms seeking recognition and rerecognition.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; collections of information for the device appeals processes have been approved under OMB control number 0910-0738.

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register** but Web sites are subject to change over time.

1. International Medical Device Regulators Forum's Medical Device Single Audit Program documents, available at http://imdrf.org/documents/documents.asp.

2. FDA Draft Guidance entitled "Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I," February 15, 2013, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339697.pdf.

Dated: September 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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