and rationales for withdrawing a standard. The guidance also provides that any interested party may request recognition of a standard. The draft guidance recommends that for recognition of a standard the request should, at a minimum, contain the following information:

- Name and electronic or mailing address of the requestor;
- Title of the standard;
- Any reference number and date;
- Proposed list of devices for which a declaration of conformity should routinely apply;
- Basis for recognition, *e.g.,* including the scientific, technical, regulatory, or other basis for such request; and
- A brief identification of the testing or performance or other characteristics of the device(s) or process(es), that would be addressed by a declaration of conformity.

Based on previous requests for recognition of standards, we estimate that FDA will receive nine requests annually. We estimate that each request will take less than 1 hour to prepare.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for recognition of a voluntary consensus standard	9	1	9	1	9

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

V. Reference

The following reference is on display with the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. OMB, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' Circular A–119 (revised). January 22, 2016. Available at: *https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf.*

Dated: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19993 Filed 9–13–18; 8:45 am]

BILLING CODE 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510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations; Availability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 or Agency) is announcing the availability of the draft guidance entitled ''510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations.'' This draft guidance provides a comprehensive look into FDA's current thinking regarding the 510(k) Third-Party (3P) Review Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the FDA Reauthorization Act of 2017 (FDARA), FDA was directed to issue draft guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P Review Program is intended to allow review of devices by 3P Review Organizations to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 13, 2018 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 collection of information by November 13, 2018.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 ''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 *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 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: Gregory Pishko, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5659, Silver Spring, MD 20993–0002, 240–402–6635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's implementation of section 523 of the FD&C Act (21 U.S.C. 360m) establishes a process for recognition of qualified third parties to conduct the initial review of premarket notification (510(k)) submissions for certain low-to-moderate risk devices eligible under the 3P Review Program. Under FDARA (Pub. L. 115–52), the criteria used to establish device eligibility in the 3P Review Program changed and FDA was directed to issue draft guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The objectives of this draft guidance are: (1) To describe the factors FDA will use in determining device type eligibility for review by 3P Review Organizations; (2) to outline FDA's process for the recognition, re-recognition, suspension, and withdrawal of recognition for 3P Review Organizations; and (3) to ensure consistent quality of work among 3P Review Organizations through Medical Device User Fee Amendments IV commitments authorized under FDARA. This draft guidance also outlines FDA's current thinking on leveraging the International Medical Device Regulators Forum's requirements for the Medical Device Single Audit Program.

Upon issuance, this draft guidance will replace the draft guidance entitled ''510(k) Third-Party Review Program—Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations'' (81 FR 62744) issued on September 12, 2016.

This draft guidance, when finalized, will supersede ''Implementation of Third-Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties'' issued on February 2, 2001, and ''Guidance for Third Parties and FDA Staff; Third-Party Review of Premarket Notifications'' issued on September 28, 2004.

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 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''510(k) Third-Party Review Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17–028 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under 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.

510(k) Third-Party Review Program (Formerly Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act)

OMB Control Number 0910–0375—Revision

Information collections (ICs) associated with the 510(k) Third-Party Review Program have been approved under OMB control number 0910–0375, ''Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act.'' When finalized, the draft guidance entitled ''510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations'' will necessitate revisions to the burden estimates in OMB control number 0910–0375.

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the FD&C Act (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this IC as follows:

Estimated Annual Reporting Burden

Requests for accreditation (initial): On average, the Agency has received one application for accreditation for 3P review per year. There is no change to this IC from the currently approved burden estimate.

Requests for accreditation (re-recognition): We have added an IC for re-recognition requests to be consistent with the guidance which states that requests for re-recognition will be handled in the same manner as initial recognition requests. Based on the estimated number of 3P Review Organizations (7) and the frequency of re-recognition (3 years), we expect to receive approximately 2 re-recognition requests per year. We expect the average burden per response to be the same as an initial request (24 hours).

510(k) reviews conducted by accredited third parties: Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for third-party review to be 147 annually; approximately 21 annual reviews for each of the 7 3P Review Organizations. This IC has been adjusted based on current trends, however, there is no program change to this IC.

Complaints: The guidance recommends that the 3P Review Organization should forward to FDA information on any complaint (*e.g.,* whistleblowing) it receives about a 510(k) submitter that could indicate an issue related to the safety or effectiveness of a medical device or a public health risk. Therefore, we have added an IC for complaints to the reporting burden. We expect to receive one forwarded complaint per year. Based on similar information collections, we estimate the average burden per complaint to be 0.25 hours (15 minutes).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation (initial) [3]	1	1	1	24	24
Requests for accreditation (re-recognition) [5]	2	1	2	24	48
510(k) reviews conducted by accredited third parties [4]	7	21	147	40	5,880
Complaints [5]	1	1	1	0.25	1
Total					5,952

[1] There are no capital costs or operating and maintenance costs associated with this IC.
(15 minutes)

Estimated Annual Recordkeeping Burden

510(k) Reviews: 3P Review Organizations should retain copies of all 510(k) reviews and associated correspondence. Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for 3P review to be 147 annually; approximately 21 annual reviews for each of the 7 3P Review Organizations. We estimate the average burden per recordkeeping to be 10 hours. The estimated number of records and recordkeepers have been adjusted based on current trends, however, there is no program change to this IC.

Records regarding qualifications to receive FDA recognition as a 3P Review Organization: Under section 704(f) of the FD&C Act (21 U.S.C. 374(f)), a 3P Review Organization must maintain records that support their initial and continuing qualifications to receive FDA recognition, including documentation of the training and qualifications of the 3P Review Organization and its personnel; the procedures used by the 3P Review Organization for handling confidential information; the compensation arrangements made by the 3P Review Organization; and the procedures used by the 3P Review Organization to identify and avoid conflicts of interest. Additionally, the draft guidance states that 3P Review Organizations should retain information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k) submission and other relevant records. Therefore, we have added an IC for ''Records regarding qualification to receive FDA recognition as a 3P Review Organization.'' Because most of the burden of compiling the records is expressed in the reporting burden for requests for accreditation, we estimate the maintenance of such records to be 1 hour per recordkeeping annually.

Recordkeeping system regarding complaints: Section 523(b)(3)(E)(iv) of the FD&C Act requires 3P Review Organizations to agree in writing that they will promptly respond and attempt to resolve complaints regarding their activities. The draft guidance

recommends that 3P Review Organizations establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Therefore, we have added an IC for ''Recordkeeping system regarding complaints.'' Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews [3]	7	21	147	10	1,470
Records regarding qualifications to receive FDA recognition as a 3P Review Organization [4]	7	1	7	1	7
Recordkeeping system regarding complaints [4]	7	1	7	2	14
Total					1,491

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

We revised our estimates for OMB control number 0910–0375 by adding new ICs, changing the title of the ICR, and adjusting the existing ICs based on current trends. Despite the addition of new ICs, the estimated burden reflects an overall decrease of 5,581 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

The draft guidance also refers to previously approved ICs found in FDA regulations. The ICs in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the ICs regarding 3P Review of medical devices under FDAMA have been approved under OMB control number 0910–0375; the ICs for the device appeals processes have been approved under OMB control number 0910–0738; the ICs in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19992 Filed 9–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by November 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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