21 CFR part. guidance, or FDA form	Topic	OMB control No.
807, subpart E and Form FDA 3654	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
820	Current Good Manufacturing Practice; Quality System Regulation.	0910–0073
312	Investigational New Drug Regulation	0910–0014
601	Biologics License Application	0910–0338

Dated: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19989 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–2018–D–2936]

Recognition and Withdrawal of Voluntary Consensus Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the draft guidance entitled ''Recognition and Withdrawal of Voluntary Consensus Standards.'' This draft guidance identifies the principles FDA uses for recognizing a standard, and it explains the extent of recognition and other supplementary information. It provides information on how you may request recognition as well as circumstances under which FDA may withdraw recognition. This draft guidance also responds to a provision of the 21st Century Cures Act (Cures Act) by updating published guidance on these topics. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. 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–2018–D–2936 for ''Recognition and Withdrawal of Voluntary Consensus Standards.'' 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 ''Recognition and Withdrawal of Voluntary Consensus Standards'' 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 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993–0002, 301–796–6287, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's standards recognition program furthers the aim of international harmonization because the same standards (or international equivalents) are relied upon by sponsors to meet other countries' regulatory requirements when appropriate. This draft guidance describes the procedures that FDA follows and the actions FDA may take during its review and evaluation of requests for standards recognition or the withdrawal of recognition. This draft guidance provides further clarity and explanation about the regulatory framework, policies, and practices when evaluating requests for recognition. This draft guidance also responds to section 3053 of the Cures Act by updating published guidance on these topics (Pub. L. 114–255). When final, this draft guidance will supersede the guidance ''CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition,'' issued on September 17, 2007.

FDA generally considers for recognition voluntary consensus standards, which are created by standards development organizations that follow a consensus process. A document issued by the Office of Management and Budget (OMB) entitled ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' commonly called OMB Circular A–119, defines the attributes or elements of a consensus process (Ref. 1). This draft guidance explains those elements and how they pertain to FDA's consideration of a standard for recognition.

The draft guidance describes the process leading up to and including recognition. We list common purposes to recognize voluntary consensus standards as well as the essential information that FDA will provide in the supplemental information sheet for the recognition of a standard. This draft guidance also discusses when FDA may withdraw recognition.

You may also request that FDA recognize a specific voluntary consensus standard. This draft guidance recommends the information you would submit to do so, and it summarizes the actions we may take to act on such a request.

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 recognition and withdrawal of voluntary consensus standards. 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 draft guidance is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Recognition and Withdrawal of Voluntary Consensus Standards'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 616 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the 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.

Request for Recognition of a Voluntary Consensus Standard

OMB Control Number 0910—NEW

The draft guidance for industry and FDA staff entitled ''Recognition and Withdrawal of Voluntary Consensus Standards'' provides guidance to industry and FDA staff about the procedures the Center for Devices and Radiological Health follows when a request for recognition of a voluntary consensus standard is received. The guidance outlines justifications for why a standard may be recognized wholly, partly, or not at all, as well as reasons

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]

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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:

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- 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