TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records regarding qualifications to receive FDA recognition as a 3PRO [3]	7	1	7	1	7
Recordkeeping system regarding complaints [3]	7	1	7	2	14
Total					1,491

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This IC has been adjusted based on current trends, however, there is no program change to this IC.
[3] This IC revises OMB control number 0910–0375 to reflect the draft guidance entitled ''510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations.''

We revised our estimates for OMB control number 0910–0375 by adding new ICs, changing the title of the IC request, and adjusting the existing ICs based on current trends. Despite the addition of new ICs, the estimated burden reflects an overall decrease of 5,580 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The draft guidance also refers to previously approved ICs found in FDA regulations.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 3P510k 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 for the Q-Submission Program (Requests for Feedback on Medical Device Submissions) have been approved under OMB control number 0910–0756.

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22345 Filed 10–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2020 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in fiscal year (FY) 2020. In addition, FDA has established a docket where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with stakeholders. This feedback is critical to the CDRH guidance program to ensure that we meet stakeholder needs.

DATES: Submit either electronic or written comments by December 16, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–1021 for ''Notice to Public of website Location of CDRH Fiscal Year 2020 Proposed Guidance Development.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations on the Medical Device User Fee Amendments of 2012, Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:

- Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the ''A-list''), and
- Annually posting a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the ''B-list'').

The Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA Reauthorization Act of 2017, (Pub. L. 115–52) maintained these commitments.

In addition, to ensure that final guidance documents continue to provide stakeholders with the Agency's current thinking, CDRH annually conducts a staged review of previously issued final guidances in collaboration with stakeholders. CDRH intends to annually provide lists of previously issued final guidances that are subject to review through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2021, CDRH expects to provide a list of the final guidance documents that issued in 2011, 2001, 1991, and 1981; the annual notice for FY 2022 is expected to provide a list of the final guidance documents that issued in 2012, 2002, 1992, and 1982, and so on.

FDA welcomes comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA–2012–N–1021 where comments on the FY 2020 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

In addition to posting the lists of prioritized device guidance documents, CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To assure the timely completion or reissuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period, or issue new draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. As part of MDUFA IV commitments, FDA reaffirmed this commitment, as resources permit.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, withdrawal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiatives

A. Metrics for FY 2019 A-List and B-List Publication

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2019 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. Some guidances requested for inclusion in the FY2019 list by stakeholders have been included as part of the FY 2020 list. In FY 2019, CDRH published 21 of 28 guidances on the FY 2019 list (17 from the A-list, 4 from the B-list).

A. Finalization of Draft Guidance Documents

Of the 23 draft guidances issued in FY 2015, CDRH finalized 87 percent within 3 years of the comment period close. Five years from the comment period close has not yet elapsed for the remaining guidances issued in FY 2015. In addition, in FY 2019, one draft guidance issued prior to October 1, 2013, remains, and CDRH has been continuing to work towards taking an action on this remaining draft guidance.

Looking forward, in FY 2020, CDRH will strive to finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2014.

B. Applicability of Previously Issued Final Guidance

At the website where CDRH has posted the ''A-list'' and ''B-list'' for FY 2020, CDRH has also posted a list of final guidance documents that issued in 2010, 2000, 1990, and 1980 for our annual review of previously issued final guidances.[1] CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH will consider the comments received from this retrospective review

[1] The retrospective list of final guidances does not include special controls documents.

when determining priorities for updating guidance documents and will revise these as resources permit.

Consistent with the Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

In FY 2019, CDRH received comments regarding guidances issued in 2009, 1999, and 1989, and has withdrawn three guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency's current thinking. The revision of several guidance documents is also being considered as resources permit.

III. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A and B lists of guidance documents, which CDRH is intending to publish during FY 2020. To access these two lists, visit FDA's website at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development.* We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (*e.g.,* newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Dated: October 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22370 Filed 10–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4839]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Registering With the Center for Veterinary Medicine's Electronic Submission System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 November 14, 2019.

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 0910–0454. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

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 on Registering With the Center for Veterinary Medicine's Electronic Submission System—21 CFR 11.2

OMB Control Number 0910–0454—Extension

FDA's ''Electronic Records; Electronic Signatures'' regulation (21 CFR part 11) requires that we identify in the Electronic Submission Docket (Docket No. FDA–1992–S–0039) the types of documents or parts of documents acceptable for official electronic submission. FDA's Center for Veterinary Medicine (CVM) has placed notifications in that docket identifying documents acceptable for electronic submission to the Center, as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of FDA's ''Electronic Records; Electronic Signatures'' regulation.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office. The CVM's Electronic Submission System (ESS) is a Center-wide solution for accepting electronic regulatory submissions. The CVM ESS is used to accept electronic submissions for animal and veterinary products.

Our Guidance for Industry (GFI) #108 entitled ''Registering with the Center for Veterinary Medicine's Electronic Submission System'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG, including how to register with the CVM ESS using Form FDA 3538, ''Electronic Submission System Participant Management.'' Registering with the CVM ESS allows respondents to send electronic regulatory submissions to the Office of New Animal Drug Evaluation, the Office of Surveillance and Compliance's Division of Animal Feeds and Division of Surveillance, and the Office of Minor Use and Minor Species Animal Drug Development.

Respondents use GFI #108 and Form FDA 3538 to facilitate the electronic submission of regulatory information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS.

Description of Respondents: The respondents are submitters of regulatory information to CVM.

In the **Federal Register** of April 16, 2019 (84 FR 15621), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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