

Dated: April 6, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2018-07544 Filed 4-11-18; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-1076]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 May 14, 2018.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0563. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice**

OMB Control Number 0910-0563—  
*Extension*

Congress enacted section 562 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-1), which directed FDA to ensure that it had adequate dispute resolution procedures to provide for appropriate review of scientific controversies between the FDA and members of regulated industry, including possible review by a scientific advisory committee. To implement this provision, we amended the general appeal regulation applicable across all FDA components (21 CFR 10.75; Internal Agency review of decisions) to provide for advisory committee review (§ 10.75(b)(2)). At the same time, and also consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures regarding scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

Accordingly, FDA developed the guidance entitled, “Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related

to Pharmaceutical Current Good Manufacturing Practice.” We intend the guidance to inform manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes about scientific and technical issues relating to current good manufacturing practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA’s assessment of corrective actions undertaken as a result of such inspections. The guidance recommends procedures that we believe encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs and Center levels and for requesting review by the dispute resolution (DR) panel. The guidance is available on our website at: <https://www.fda.gov/downloads/drugs/guidances/ucm070279.pdf>, along with additional information regarding the resolution of scientific disputes at FDA.

In the **Federal Register** of October 27, 2017 (82 FR 49832), we published a notice soliciting public comment on the proposed collection of information. Although no comments were received, we are reconsidering the usefulness of the guidance document in light of changing Agency procedures. Consistent with our regulations at 21 CFR part 10.115 we invite comment on our guidance documents at any time. Ultimately, as our resources permit, we hope to either revise, replace, or withdraw the subject guidance document, however, until that time the guidance remains available. Accordingly, we are seeking to extend OMB approval of the information collection and estimate the burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Annual frequency per response	Total annual responses	Average burden per response	Total hours
Requests for tier-one DR	2	1	2	30	60
Requests for tier-two DR	1	1	1	8	8
Total .....	.....	.....	.....	.....	68

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection.

As reflected in table 1, we estimate only a nominal burden for the information collection and assume: (1) That two manufacturers will submit two requests annually for tier-one DR; (2)

that there will be one appeal to the DR panel (tier-two DR); (3) that it will take respondents approximately 30 hours to prepare and submit each tier-one DR request; and (4) that it will take

approximately 8 hours to prepare and submit each tier-two DR request. We base this estimate on our experience with the information collection. There has been no increase in the burden

estimate since the previous OMB approval.

Dated: April 6, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-6162]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification of the Intent To Use An Accredited Person Under the Accredited Persons Inspection Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 May 14, 2018.

**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 0910-0569. 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.

**Notification of the Intent To Use An Accredited Person Under the Accredited Persons Inspection Program**

*OMB Control Number 0910-0569—Extension*

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding paragraph (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled “Manufacturer’s Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.” This guidance superseded the Agency’s previous guidance regarding

requests for third-party inspection and may be found on the internet at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085252.pdf*. The guidance is intended to assist device establishments in determining whether they are eligible to participate in the Accredited Persons (AP) Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 10 of these manufacturers may use an AP in any given year.

In the **Federal Register** of November 21, 2017 (82 FR 55379), 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity/21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification regarding use of an AP—374(g) .....	10	1	10	15	150

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the last approval of this information collection, we have updated the estimated number of respondents from 20 to 10 respondents per year, based on the reduced number of

notifications received in recent years. This adjustment has resulted in a 150-hour reduction to the total hour burden estimate.

Dated: April 6, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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