4164-01-P

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 0910-0563. 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, 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 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[1]

Activity	No. 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

[1] 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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