4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1011]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products

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 0910-0759. 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.

Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products--21 CFR 310.306, 314.81(b)(3)(iii), and 600.82

OMB Control Number 0910-0759--Extension

Sections 310.306, 314.81(b)(3)(iii), and 600.82 (21 CFR 310.306, 314.81(b)(3)(iii), and 600.82) were modified to implement sections 506C and 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c and 356e) as amended by the Food and Drug Administration Safety and Innovation Act. Under these sections, applicants with an approved new drug application (NDA) or abbreviated new drug application (ANDA) for a covered drug product, manufacturers of a covered drug product marketed without an approved application, and applicants with an approved biologics license application (BLA) for a covered biological product (including certain applications of blood or blood components) must notify FDA in writing of a permanent discontinuance of the manufacture of the drug or biological product, or an interruption in manufacturing of the drug or biological product, that is likely to lead to a meaningful disruption in the applicant's supply (or a significant disruption for blood or blood components) of that product. The notification is required if the drug or biological product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, and if the drug or biological product is not a radiopharmaceutical drug product.

The regulations also require that the notification include the following information: (1) the name of the drug or biological product subject to the notification, including the National Drug Code Directory (NDC) (or, for a biological product that does not have an NDC, an

alternative standard for identification and labeling that has been recognized as acceptable by the Center Director); (2) the name of each applicant of the drug or biological product; (3) whether the notification relates to a permanent discontinuance of the drug or biological product or an interruption in manufacturing of the product; (4) a description of the reason for the permanent discontinuance or interruption in manufacturing; and (5) the estimated duration of the interruption in manufacturing. The notification must be submitted to FDA electronically at least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing. If 6 months' advance notice is not possible because the permanent discontinuance or interruption in manufacturing was unanticipated 6 months in advance, the applicant must notify FDA as soon as practicable, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

If an applicant fails to submit the required notification, FDA will issue a letter informing the applicant or manufacturer of its noncompliance. The applicant must submit to FDA, not later than 30 calendar days after FDA issues the letter, a written response setting forth the basis for noncompliance and providing the required notification.

Description of Respondents: Applicants of prescription drugs and biological products subject to an approved NDA, ANDA, or BLA, and manufacturers of prescription drug products marketed without an approved ANDA or NDA, if the product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, or is not a radiopharmaceutical product. If the BLA applicant is a manufacturer of blood or blood components, it is only subject to these regulations if it manufactures a significant percentage of the nation's blood supply.

Burden Estimates: Based on the number of drug and biological product shortage related notifications we have seen in the past 12 months, we estimate that annually a total of approximately 75 respondents ("No. of Respondents" in table 1) will notify us of a permanent discontinuance of the manufacture of a drug or biological product or an interruption in manufacturing of a drug or biological product that is likely to lead to a meaningful disruption in the respondent's supply of that product. We estimate that these respondents will submit annually a total of approximately 352.5 notifications as required under §§ 310.306, 314.81(b)(3)(iii), and 600.82. We estimate 4.7 notifications per respondent, because a respondent may experience multiple discontinuances or interruptions in manufacturing in a year that requires notification ("No. of Responses per Respondent" in table 1). We also estimate that preparing and submitting these notifications to FDA will take approximately 2 hours per respondent ("Average Burden per Response" in table 1).

In the *Federal Register* of April 13, 2018, (83 FR 16108), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Notifications required under §§ 310.306 (unapproved drugs), 314.81(b)(3)(iii) (products approved under an NDA or ANDA), and 600.82 (products approved under a BLA)	75	4.7	352.5	2	705

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

The estimated burden for this information collection has changed since the previous OMB approval. The current burden is based on the number of actual new notifications received including notifications that were counted previously under the OMB approval for the interim

final rule entitled “Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products” (80 FR 38915, July 8, 2015) (OMB control number 0910-0699).

Dated: July 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-15948 Filed: 7/25/2018 8:45 am; Publication Date: 7/26/2018]