4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0610]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

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 0910-0701. 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 Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

OMB Control Number 0910-0701--Extension

This information collection supports the above captioned Agency guidance. The guidance includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) instructions for reporting adverse events and (2) a plan for submitting stored reports that were not submitted

within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records.

In the *Federal Register* of October 31, 2017 (82 FR 50431) we published a notice inviting public comment of the proposed collection of information. Although one comment was received, it did not respond to any of the four information collection topics solicited in the notice under the PRA. We therefore made no changes to our estimate of the burden for the information collection, which remains as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Type of Reporting	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Notify FDA when normal reporting is not feasible.	500	1	500	8	4,000

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

Type of Recordkeeping	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Hours Per Record	Total Hours
Add adverse event reporting plan to COOP.	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism.	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored.	500	1	500	8	4,000
Total					258,000

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

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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