4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0915]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

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 0910-0636. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 Nonprescription Human Drug Products Marketed Without an Approved Application

(OMB Control Number 0910-0636)--Extension

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) (21 U.S.C. 352(b)(1)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States. FDA is requesting public comment on estimates of annual submissions from these respondents, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462) and described in the guidance. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) (21 U.S.C. 379aa(b)(1)) of the FD&C Act, including follow-up reports under 760(c)(2) (21 U.S.C. 379aa(c)(2)) of the FD&C Act, and how to submit these reports. The estimates for the annual reporting and recordkeeping burdens are based on FDA data on the number of adverse drug experience reports submitted for nonprescription drug products marketed without an approved application, including FDA's knowledge about the time needed to prepare the reports and to maintain records.

In the Federal Register of January 23, 2015 (80 FR 3608), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one

comment. The comment requested that we increase the reporting burden estimates from 2 hours to 6 hours and the recordkeeping burden estimates from 5 hours to 8 hours. The comment said although there may be circumstances where FDA's estimates for reporting and recordkeeping may be accurate, the comment contended that, in its experience, the approximations are underestimated. The comment said that as many as 6 hours may be required to complete a single serious adverse event report, especially when the sponsor's medical and quality review teams are involved, and that as many as 8 hours may be required to maintain all relevant records for a single adverse event report as stipulated by statute.

FDA Response: We have reconsidered our estimates, and agree with the comment that there may be circumstances where 6 hours would be needed to prepare and submit a report to us and 8 hours may be needed for recordkeeping. We have revised our reporting and recordkeeping burden estimates accordingly.

Based on FDA data, we estimate between 10,000 and 15,000 (i.e., approximately 12,500) total annual responses from approximately 50 respondents for nonprescription drugs marketed without an approved application, and we also estimate that each submission will take approximately 6 hours to prepare and submit.

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reports of serious adverse drug events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	6	75,000

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

Section 760(e) (21 U.S.C. 379aa(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance document recommends that respondents maintain

records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any follow-up reports. We estimate that there are approximately 20,000 records per year maintained by approximately 200 respondents, and that it takes approximately 8 hours to maintain each record.

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

Activity	No of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	8	160,000

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

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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