

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0386]

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Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.” This draft guidance document provides guidance to industry on postmarketing serious adverse event reporting for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application. It gives guidance on the minimum data elements that should be included in a serious adverse event report, the label that should be included with the report, reporting formats for paper and electronic submissions, and how and where to submit the reports. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on reporting for dietary supplements, is announced elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit

written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of the draft guidance, including comments regarding proposed collection of information, to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kathleen Frost, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4312, Silver Spring, MD 20993–0002, 301–796–2380.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.” Public Law 109–462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which was signed by the President on December 22, 2006, states: “Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that

should be included in a serious adverse event report as described under the amendments made by this Act” (section 2(e)(3)). Public Law 109–462 also requires certain postmarketing safety reports for dietary supplements.

Public Law 109–462 amends the Federal Food, Drug, and Cosmetic Act (the act) to add safety reporting requirements for nonprescription drug products that are marketed without an approved application. In accordance with section 760(b) of the act (21 U.S.C. 379aa), the manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug marketed in the United States without an approved application (referred to as the responsible person) must submit to FDA any report of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug. In addition, the responsible person must submit followup reports of new medical information related to a submitted serious adverse event report that is received within 1 year of the initial report (section 760(c)(2) of the act). The guidance document provides information on: (1) The minimum data elements that should be included in a serious adverse event report; (2) the label that should be included with the report; (3) reporting formats for paper and electronic submissions; and (4) how and where to submit the reports.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on postmarketing adverse event reporting for nonprescription human drug products marketed without an approved application. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative

approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity

of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Postmarketing Adverse Event Reporting and Recordkeeping for Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the act) appears on the label of a nonprescription drug marketed in the United States.

Burden Estimate: FDA is requesting public comment on estimates of annual submissions from these respondents, expected in 2008, as required by Public Law 109–462 and described in this guidance. This guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the act, including follow-up reports under 760(c)(2) of the act, and how to submit these reports. The estimates for annual reporting burden and recordkeeping are based on FDA’s knowledge of adverse drug experience reports historically submitted per year for prescription drug products and for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports and to maintain records.

FDA receives approximately 2,500 serious adverse event reports for nonprescription drug products marketed under approved applications, which

comprise approximately 20 percent of the overall nonprescription drug market. Based on this experience, we estimate between 10,000 and 15,000 (i.e., 12,500) total annual responses for nonprescription drugs marketed without an approved application. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Reports of serious adverse drug events (21 U.S.C. 379aa(b) and (c))	50	250	12,500	2	25,000
Total					25,000

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

Section 760(e) of the 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 draft guidance recommends that responsible persons maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports. Although the guidance does not provide recommendations on recordkeeping activities generally under section 760(e) of the act, FDA is providing an estimate for the burden of this collection. Historically, serious adverse event reports comprise approximately two-thirds, and nonserious adverse event reports comprise approximately one-third, of the total number of postmarketing adverse event reports associated with drugs and biologic therapeutics (except vaccines) received by FDA. Based on this generalization, FDA estimates the total annual records to be approximately 20,000 records per year. FDA estimates that it takes 5 hours to maintain each record and the recordkeeping burden as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total					100,000

¹There 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 10-10-07

October 10, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins