DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0274]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with adverse event reporting and recordkeeping for dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA).

DATES: Submit either electronic or written comments on the collection of information by May 22, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793, *Denver.Presley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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, including each proposed extension of an existing 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 in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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 of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act —21 U.S.C. 379aa–1(b)(1) (OMB Control Number 0910–0635)—Extension

The DSNDCPA (Public Law 109–462, 120 Stat. 3469) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting and recordkeeping for dietary supplements and nonprescription drugs marketed without an approved application. Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1)) requires the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the FD&C Act (21 U.S.C. 343(e)(1))) appears on the label of a dietary supplement marketed in the United States to submit to FDA all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (FDA 3500A) when submitting a serious adverse event report to FDA. In addition, under section 761(c)(2) of the FD&C Act, the submitter of the serious adverse event report (referred to in the statute as the ''responsible person'') is required to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

Section 761(e)(1) of the FD&C Act (21 U.S.C. 379aa–1(e)(1)) requires that responsible persons maintain records related to the dietary supplement adverse event reports they receive, whether or not the adverse event is serious. Under the statute, the records must be retained for a period of 6 years.

As required by section 3(d)(3) of the DSNDCPA, FDA issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. In the **Federal Register** of July 14, 2009 (74 FR 34024), FDA announced the availability of guidance entitled ''Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides FDA's recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

The guidance recommends that the responsible person document its attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) Communications between the responsible person and the initial reporter of the adverse event and between the responsible person and any other person(s) who provided information about the adverse event, (2) the responsible person's serious adverse event report to FDA with attachments, (3) any new information about the adverse event received by the responsible person, and (4) any reports to FDA of new information related to the serious adverse event report.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 U.S.C. 379aa–1(b)(1)—Serious adverse event reports for dietary supplements	480	17	8,160	2	16,320
21 U.S.C. 379aa–1(c)(2)—Followup reports of new medical information	120	17	2,040	1	2,040
					18,360

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

This estimate is based on FDA's experience with similar adverse event reporting programs and the number of serious adverse event reports and followup reports received in the past 2 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting. In 2007, we estimated in the final rule entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' (72 FR 34752, June 25, 2007) that there were 1,460 such firms. FDA estimates that, in 2012, there are approximately 1,600 such firms, based on the estimate of 1,460 provided in the rule, with a two to three percent annual rate of growth applied.

FDA received 830 initial serious adverse event reports in FY2010. The number of reports more than doubled to 1,777 in FY2011. We expect this trend to continue and, in fact, increase due to continued industry compliance with mandatory reporting rules. Based on this, FDA expects to receive over the next 3 years an increasing number of reports per year: We estimate that we will receive 3,500 in 2012; 7,000 in 2013; and 14,000 in 2014; for an annual average of 8,166.66 per year, rounded to 8,160. Based on the Agency's records, the average number of initial reports per year on a per firm basis during 2010 and 2011 was 17. Thus, FDA estimates that, on average over the next 3 years, 480 firms will file 17 initial dietary supplement serious adverse event reports, for a total of 8,160 total annual responses.

FDA estimates that it will take respondents an average of 2 hours per report to collect information about a serious adverse event associated with a dietary supplement and report the information to FDA on Form FDA 3500A. Thus, the estimated total annual hour burden of initial dietary supplement serious adverse event reports is 16,320 hours (8,160 responses $\times$ 2 hours) as shown in row 1 of Table 1.

If a respondent that has submitted a serious adverse event report receives new information related to the serious adverse event within 1 year of submitting the initial report, the respondent must provide the new information to FDA in a followup report. FDA estimates that 25 percent of serious adverse event reports related to dietary supplements will have a followup report submitted, resulting in approximately 2,040 followup reports submitted annually ($8{,}160 \times 0.25 = 2{,}040$). Assuming that 25 percent of submitters of initial reports will submit followup reports ($480 \times 0.25 = 120$) and the average number of followup reports per year per firm to be 17, FDA estimates that, on average over the next 3 years, 120 firms will file 17 followup reports, for a total of 2,040 total annual responses. We estimate that each followup report will require an hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the guidance. The estimated total annual hour burden for followup reports of new information is 2,040 hours (2,040 responses $\times$ 1 hour) as shown in row 2 of Table 1.

The total reporting hour burden is 18,360 hours, which equals the burden for the mandatory reports (16,320) plus the burden for the followup new information (2,040).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 U.S.C. Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
Dietary Supplement Adverse Event Records (21 U.S.C. 379aa–1(e)(1)).	1,600	74	118,400	0.5 (30 minutes).	59,200

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

All 1,600 dietary supplement manufacturers, packers, or distributors, are subject to serious adverse event mandatory recordkeeping, thus FDA estimates that there are a total of 1,600 recordkeepers. FDA further estimates that each recordkeeper will keep approximately 74 records per year, for a total of 118,400 records. The Agency estimates that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hours, per record. Therefore, 118,400 records $\times$ 0.50 hours = 59,200 total hours. FDA bases its estimates on its experience with similar adverse event reporting programs.

Once the documents pertaining to an adverse event report have been assembled and filed under the Safety Reporting Portal, FDA expects the records retention burden to be minimal, as the Agency believes most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: March 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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