TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

	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

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

The guidance also 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 document does not provide recommendations on all the recordkeeping activities required under section 760(e) of the act, we are providing an estimate for this burden. 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, we estimate the total annual records to be approximately 20,000 records per year, and the number of respondents to be approximately 200. We also estimate that it takes approximately 5 hours to maintain each record.

TABLE 2.— ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	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
Total					100,000

[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 collection is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21345 Filed 9–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0372] (formerly Docket No. 2007D–0388)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 October 15, 2008.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, ''Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910–NEW)

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors of dietary supplements marketed in the United States.

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting and recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application.

Under section 761(b)(1) of the act (21 U.S.C. 379aa–1(b)(1)), the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the act (21 U.S.C. 343(e)(1))) appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary

supplement in the United States, accompanied by a copy of the product label. In addition, under section 761(c)(2) of the 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. Under section 761(e)(1) of the act, responsible persons are required to maintain records related to dietary supplement adverse event reports they receive, whether or not the adverse event is serious. These requirements became effective on December 22, 2007.

As required by section 3(d)(3) of the DSNDCPA, FDA is issuing guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. The draft guidance entitled ''Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act,'' was issued October 15, 2007, and is consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports of new medical information. In accordance with the statutory requirements that serious adverse event reports for dietary supplements be submitted via MedWatch (section 761(d) of the act) and that FDA consolidate all information related to a serious adverse event into a single report (section 761(c)(3) of the act), the draft guidance directs the responsible person to submit serious adverse event reports on MedWatch Form 3500A and to attach a copy of the initial serious adverse event report on Form 3500A as part of any followup report of new medical information. We are also providing guidance on records maintenance and access for serious and non-serious adverse event reports and related documents.

In the **Federal Register** of October 15, 2007 (72 FR 58313), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment related to the information collection. The comment disagreed with FDA's proposed estimate of the annual recordkeeping burden associated with dietary supplement adverse events. However, the commenter did not provide an alternative estimate or compelling information that the estimate provided by FDA was not a reasonable upper-bound estimate. Since the receipt of the comment, the mandatory reporting of serious adverse events for dietary supplements to FDA has come into effect (on December 22, 2007). Thus, FDA now has data on mandatory dietary supplement adverse event reports to use in revising our reporting burden estimate. For the first quarter of 2008 (January 1 to April 15), FDA has received 214 mandatory reports of serious adverse events related to dietary supplements. Therefore, FDA revises our annual burden estimate from 960 mandatory reports to 856 mandatory reports of serious adverse events related to dietary supplements. FDA requests comments on this estimate.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Serious adverse event reports for dietary supplements (21 U.S.C. 379aa–1(b)(1))	71.3333	12	856	2	1,712
Followup reports of new medical information (21 U.S.C. 379aa–1(c)(2))	17.83333	12	214	1	214
Total					1,926

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

FDA's Center for Drug Evaluation and Research estimates it will take respondents a total of 2 hours to collect information about a serious adverse event associated with an over-the-counter drug marketed without an approved application and report the information to FDA on MedWatch Form 3500A. That time burden estimate is based on FDA's knowledge of the adverse drug experience reports submitted to the agency for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports. FDA believes that the time for a dietary supplement firm to collect information about a serious adverse event associated with a dietary supplement and report the information to FDA will be approximately the same, as MedWatch Form 3500A will be used in both cases; therefore, we also estimate this time burden at 2 hours per report. The estimated total annual burden for dietary supplement serious adverse event reports is shown in row 1 of table 1 of this document.

If a firm that has submitted a serious adverse event report receives new medical information related to the serious adverse event within 1 year of submitting the initial report, the firm must provide the new medical information to FDA in a followup report. Given our limited experience with mandatory dietary supplement adverse event reporting, we do not have any information on the number of followup reports of new medical information that will be submitted to FDA each year. We expect followup medical information to be reported for some percentage of the 856 serious adverse event reports we estimate receiving annually. In the absence of data that would support a more precise estimate, we will assume that 25 percent of the 856 serious adverse event reports for dietary supplements will have a followup report submitted. FDA requests comments on this estimate. We estimate that each followup report will require 1 hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the draft guidance. We assume the followup report will take less time than the initial serious adverse event report, as the responsible person will not need to fill out Form 3500A for the followup report. FDA requests comments on whether the burden estimate of 1 hour is reasonable for this information collection. The

estimated total annual burden for followup reports of new medical information is shown in row 2 of table 1 of this document.

As previously noted, section 761(e)(1) of the act requires that responsible persons maintain records related to 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. The draft guidance provides FDA's recommendations as to what records industry should maintain to satisfy the statutory recordkeeping requirement.

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 with any other person(s) who provided information about the adverse event; (2) (for serious adverse events only) the responsible person's serious adverse event report to FDA on MedWatch Form 3500A, with attachments; (3) any new medical information about the adverse event received by the responsible person; (4) (for serious adverse events only) any reports to FDA of new medical information related to the serious adverse event report. We estimate that assembling and filing these records, including any necessary photocopying, will take approximately 0.5 hours per adverse event report received by the responsible person.

Once the documents pertaining to an adverse event report have been assembled and filed, 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. FDA requests comment on current adverse event recordkeeping practices in the dietary supplement industry, including the length of time such records are typically kept.

According to a 2001 report by the Office of the Inspector General, between 1994–1999 FDA received 2,547 adverse event reports involving dietary supplements, or about 500 reports per year, on average. According to the report, the actual number of adverse events relating to dietary supplements is likely to be at least 100 times that many, or more than 50,000 adverse events per year. Given that we have limited data on how many adverse events will be reported each year to the responsible person, we are using the 50,000 per year figure as an upper-bound estimate of reporting. This is almost certainly an overestimate of the number of reports the firms will receive, as it is unlikely that every adverse event that occurs will be reported to the responsible person. FDA requests comments on this estimate.

We estimated in the economic impact analysis of the Dietary Supplement Good Manufacturing Practices final rule (the GMP final rule) (72 FR 34752, June 25, 2007) that there are 1,460 manufacturers, packers, and holders of dietary supplements (72 FR 34752 at 34920). We assume that the estimated 50,000 adverse event reports related to dietary supplements will be spread evenly among these firms. The estimate of the number of manufacturers, packers, and holders of dietary supplements from the GMP final rule is FDA's best estimate of the number of firms that are ''responsible persons'' who must comply with the recordkeeping requirements of the DSNDCPA; however, it is not a precise estimate because the number of dietary supplement establishments covered by the GMP final rule is likely to be larger than the number of ''responsible persons,'' where a ''responsible person'' is a dietary supplement manufacturer, packer, or distributor whose name is listed on the label of a dietary supplement marketed in the United States (see section 761(b)(1) of the act). Thus, FDA's estimate for the number of respondents in table 2 may be over inclusive. FDA requests comments on the number of firms that would be subject to the recordkeeping requirements of the DSNDCPA.

The estimated total annual recordkeeping burden under the statute and this guidance is shown in table 2 of this document.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Record	Total Hours
Dietary supplement adverse event records (21 U.S.C. 379aa–1(e)(1))	1,460	4.2465	50,000	0.5	25,000

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

[2] For purposes of estimating the number of records and hours per record, a ''record'' means all records kept for an individual adverse event report received by the responsible person.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0480]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2009 for user fees under the Animal Drug User Fee Act program (ADUFA). The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA I), and the Animal Drug User Fee Amendments of 2008 (ADUFA II), authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug