OGE's SES Performance Review Board as it was most recently published at 72 FR 54666–54667 (September 26, 2007).

Approved: September 9, 2008.

Robert I. Cusick,

Director, Office of Government Ethics.

The following officials have been appointed as regular members of the SES Performance Review Board of the Office of Government Ethics:

Joseph E. Gangloff [Chair], Deputy Director for Agency Programs, Office of Government Ethics;

Don W. Fox [Alternate Chair], General Counsel, Office of Government Ethics;

Daniel L. Koffsky, Special Counsel, Office of Legal Counsel, Department of Justice;

David Maggi, Chief, Ethics Law and Programs Division, Office of the Assistant General Counsel for Administration, Department of Commerce; and

Robert A. Shapiro, Associate Solicitor for Legal Counsel, Department of Labor.

[FR Doc. E8–21447 Filed 9–12–08; 8:45 am]

BILLING CODE 6345–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0434] (formerly Docket No. 2007D–0386)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 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 ''Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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

Public Law 109–462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, amended 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). Section 760(e) of the act also requires that responsible persons maintain records of nonprescription drug adverse event reports, whether or not the event is serious, for a period of 6 years. 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.

Title: Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, or distributors whose name appears on the label of a nonprescription drug marketed in the United States without an approved application.

Burden Estimate: FDA is requesting public comment on estimates of the number of annual submissions from these respondents and recordkeeping, as required by Public Law 109–462 and described in the guidance ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.'' The estimates for annual reporting and recordkeeping are based on FDA's knowledge of adverse drug experience reports historically submitted annually 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 data, we estimate between 10,000 and 15,000 (i.e., 12,500) total annual responses from approximately 50 respondents for nonprescription drugs marketed without an approved application, and that each submission will take approximately 2 hours to prepare and submit to FDA.

In the **Federal Register** of October 15, 2007 (72 FR 58316), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

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
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