document supersedes ''Updated 510(k) Sterility Review Guidance K90–1'' dated August 30, 2002.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on submission and review of sterility information in 510(k)s for devices labeled as sterile. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1615 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01093 Filed 1–20–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0372]

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 February 22, 2016.

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 0910–0635. 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.

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 Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) (Pub. L. 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 non-prescription 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 us 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 follow-up 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, we 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), we 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 follow-up reports. The guidance also provides our 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 their 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 us with attachments; (3) any new information about the adverse event received by the responsible person; (4) any reports to us of new information related to the serious adverse event report.

In the **Federal Register** of October 21, 2015 (80 FR 63797), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate 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	170	17	2,860	2	5,720
21 U.S.C. 379aa–1(c)(2)— follow-up reports of new medical information	42	17	715	1	715
Total					6,435

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

This estimate is based on our experience with similar adverse event reporting programs and the number of serious adverse event reports and follow-up reports received in the past 3 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting.

We received 2,435 initial serious adverse event reports in Fiscal Year (FY) 2012, 3,414 in FY2013, and 2,745 in FY2014. We averaged these figures (2,860 rounded to the nearest ten) as a basis for our estimated number of annual reports. We also used an average of the number of firms filing reports (170 rounded to the nearest ten). Finally, we estimate 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 us on Form FDA 3500A. Thus, the estimated burden associated with submitting initial dietary supplement serious adverse event reports is 5,720 hours (2,860 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 us in a follow-up report. We estimate that 25 percent of serious adverse event reports related to dietary supplements will have a follow-up report submitted, resulting in approximately 715 follow-up reports submitted annually ($2{,}860 \times 0.25 = 715$). Dividing the annual number of reports among the 170 firms reporting results in approximately 17 reports for 42 respondents. We estimate that each follow-up 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. Thus the estimated burden for follow-up reports of new information is 715 hours (715 responses $\times$ 1 hour) as shown in row 2 of table 1.

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 recordkeeping	Total hours
Dietary supplement adverse event records (21 U.S.C. 379aa–1(e)(1))	1,700	74	125,800	0.5	62,900

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

All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event recordkeeping. We estimate that there are 1,700 such respondents, based on the figure 1,460 as provided in our final rule of June 25, 2007 (72 FR 34751), on the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, and factoring a two percent annual growth rate. Estimating that each recordkeeper will keep approximately 74 records per year results in an annual burden of 125,800 records. Estimating that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hours, per record, results in an annual burden of 62,900 hours (125,800 records $\times$ 0.50 hours = 62,900 total hours.

Once the documents pertaining to an adverse event report have been assembled and filed pursuant to the Safety Reporting Portal, we expect the records retention burden to be minimal, as we believe 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: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01103 Filed 1–20–16; 8:45 am]

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