Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MEVACOR (lovastatin) tablets, 20 mg and 40 mg, are the subject of NDA 19–643, held by Merck & Co. Inc., and initially approved on August 31, 1987. MEVACOR is indicated: (1) To reduce the risk of myocardial infarction, unstable angina, and coronary revascularization procedures in individuals without symptomatic cardiovascular disease, average to moderately elevated total cholesterol (total-C) and low-density lipoprotein cholesterol (LDL–C), and below average high-density lipoprotein cholesterol; (2) to slow the progression of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower total-C and LDL–C to target levels; and (3) as an adjunct to diet for the reduction of elevated total-C and LDL–C levels in patients with primary hypercholesterolemia (Types IIa and IIb), when the response to diet restricted in saturated fat and cholesterol and to other nonpharmacological measures alone has been inadequate. MEVACOR is also indicated as an adjunct to diet to reduce total-C, LDL–C, and apolipoprotein B levels in adolescent boys and girls who are at least 1 year post-menarche, 10–17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy, the following findings are present: (1) LDL–C remains >189 mg/deciliter (dL) or (2) LDL–C remains >160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors are present in the adolescent patient.

MEVACOR (lovastatin) tablets, 20 mg and 40 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Winifred M. Begley submitted a citizen petition dated September 10, 2015 (Docket No. FDA–2015–P–3319), under 21 CFR 10.30, requesting that the Agency determine whether MEVACOR (lovastatin) tablets, 20 mg and 40 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MEVACOR (lovastatin) tablets, 20 mg and 40 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEVACOR (lovastatin) tablets, 20 mg and 40 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MEVACOR (lovastatin) tablets, 20 mg and 40 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MEVACOR (lovastatin) tablets, 20 mg and 40 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to MEVACOR (lovastatin) tablets, 20 mg and 40 mg. Additional ANDAs that refer to these products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01096 Filed 1–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0611]

Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.'' This guidance updates and clarifies the information regarding sterilization processes that FDA recommends sponsors include in 510(k)s for devices labeled as sterile. This guidance document also provides details about the pyrogenicity information that FDA recommends sponsors include in a 510(k) submission.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time. The recommendations in this guidance will be implemented on March 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2008–D–0611 for ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile; Guidance for Industry and Food and Drug Administration Staff; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002.

Alternatively, you may submit written requests for single copies of the guidance document to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, FDA has received an increasing number of 510(k)s for devices labeled as sterile that are sterilized during the manufacturing process by methods other than the traditionally used methods (*i.e.,* steam, dry heat, ethylene oxide (EO), and radiation). FDA has experience with some of the other methods and now considers them to be established methods. However, there may be alterations to the more recently developed methods. In addition, original, innovative sterilization technologies are being developed and proposed. FDA considers these to be novel methods, which carry a substantial risk of inadequate sterility assurance. Consequently, devices sterilized using these technologies may not comply with Good Manufacturing Practice. Failure to assure sterility presents a serious risk to human health because of the risk of infection. Therefore, we intend to inspect the manufacturing facility before clearing a 510(k) for a device that is sterilized by a novel sterilization process. We believe inspecting the manufacturing facility for devices sterilized using these novel sterilization technologies will help ensure the safety and effectiveness of these devices and mitigate the risks to human health.

This guidance document updates and clarifies the information regarding sterilization processes that we recommend sponsors include in 510(k)s for devices labeled as sterile. This guidance document also provides details about the pyrogenicity information that we recommend sponsors include in a 510(k) submission. In the **Federal Register** of December 12, 2008 (73 FR 75724), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by March 12, 2009. FDA considered the public comments received and revised the guidance, where applicable. This

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]

BILLING CODE 4164–01–P

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