VERIFIEDPointFederatedFullName: Merck & Co. Inc.

SUPPORTING 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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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 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under 21 CFR 10.30, requesting that the Agency determine whether MEVACOR (lovastatin) tablets, 20 mg and 40 mg, were withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that MEVACOR (lovastatin) tablets, 20 mg and 40 mg, were not withdrawn for reasons of safety or effectiveness.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.
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
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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/
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Docket: For access to the docket to
read background documents or the
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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; Guidance for Industry and Food
and Drug Administration Staff;
Availability.” Received comments will
be placed in the docket and, except for
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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
request. The guidance may also be
obtained by mail by calling CBER at 1–

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
despite these to be novel methods, which carry
a substantial risk of inadequate sterility
assurance. Consequently, devices
derived from these technologies may
cannot 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
despite 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
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. 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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