

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section or other category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-notification Consultation or Master File (concerning a food contact substance). <sup>8</sup>	FDA 3480	190	1	190	0.5	95
Amendment to an existing notification (170.101), amendment to a Pre-notification Consultation, or amendment to a Master File (concerning a food contact substance). <sup>9</sup>	FDA 3480A.	100	1	100	0.5	50
171.1 Indirect Food Additive Petitions .....	N/A .....	1	1	1	10,995	10,995
Use of Recycled Plastics in Food Packaging: Chemistry Considerations.	N/A .....	10	1	10	25	250
Total .....	.....	.....	.....	.....	.....	31,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Notifications for food contact substance formulations and food contact articles. These notifications require the submission of Form FDA 3479 (“Notification for a Food Contact Substance Formulation”) only.

<sup>3</sup> Duplicate notifications for uses of food contact substances.

<sup>4</sup> Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.

<sup>5</sup> Notifications for uses that are the subject of moderately complex food additive petitions.

<sup>6</sup> Notifications for uses that are the subject of very complex food additive petitions.

<sup>7</sup> These notifications require the submission of Form FDA 3480.

<sup>8</sup> These notifications recommend the submission of Form FDA 3480.

<sup>9</sup> These notifications recommend the submission of Form FDA 3480A.

The estimates in table 1 are based on our current experience with the food contact substance notification program and informal communication with industry.

Beginning in row 1 we estimate 10 respondents will submit two notifications annually for food contact substance formulations (Form FDA 3479), for a total of 20 responses. We calculate a reporting burden of 2 hours per response, for a total of 40 hours. In row 2 we estimate six respondents. We believe the hourly burden for preparing these notifications will primarily consist of the manufacturer or supplier completing Form FDA 3480, verifying that a previous notification is effective and preparing necessary documentation. We estimate one submission for each respondent, for a total of six responses. We calculate a reporting burden of 25 hours per response, for a total of 150 hours.

In rows 3, 4, and 5 we identify three tiers of FCNs that reflect different levels of burden applicable to the respective information collection items (denoted as Categories C, D, and E). We estimate 6 respondents will submit 2 Category C submissions annually, for a total of 12 responses. We calculate a reporting burden of 120 hours per response, for a total burden of 1,440 hours. We estimate 42 respondents will submit 2 Category D submissions annually, for a total of 84 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 12,600 hours. We estimate 38 respondents will submit 1 Category E submission annually, for a total of 38 responses. We calculate a

reporting burden of 150 hours per response, for a total burden of 5,700 hours.

In row 6 we estimate 190 respondents will submit information to a pre-notification consultation or a master file in support of FCN submission using Form FDA 3480. We calculate a reporting burden of 0.5 hours per response, for a total burden of 95 hours. In row 7 we estimate 100 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, an amendment to a pre-notification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

In row 8 we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours.

Finally, in row 9 we estimate ten respondents will utilize the recommendations in the guidance document entitled, “Use of Recycled Plastics in Food Packaging: Chemistry Considerations,” to develop the additional information for one such submission annually, for a total of 10 responses. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

Dated: January 14, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–P–3319]

#### Determination That MEVACOR (Lovastatin) Tablets, 20 Milligrams and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that MEVACOR (lovastatin) tablets, 20 milligrams (mg) and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

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.*

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## 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: