



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Determination That MEVACOR (Lovastatin) Tablets, 20 Milligrams and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA or Agency) has determined that MEVACOR (lovastatin) tablets, 20 milligrams (mg) and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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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