

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-P-0416]

Determination That TRAVATAN (Travoprost Ophthalmic Solution), 0.004%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that TRAVATAN (travoprost ophthalmic solution), 0.004%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for travoprost ophthalmic solution, 0.004%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Olivia J.E. Morris, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6260, Silver Spring, MD 20993-0002, (301) 796-3601.

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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

TRAVATAN (travoprost ophthalmic solution), 0.004%, is the subject of NDA 21-257, held by Alcon Pharmaceuticals, Ltd., and initially approved on March 16, 2001. TRAVATAN is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

TRAVATAN (travoprost ophthalmic solution), 0.004%, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated May 25, 2011 (Docket No. FDA-2011-P-0416), under 21 CFR 10.30, requesting that the Agency determine whether TRAVATAN (travoprost ophthalmic solution), 0.004%, was voluntarily withdrawn or withheld 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 TRAVATAN (travoprost ophthalmic solution), 0.004%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TRAVATAN (travoprost ophthalmic solution), 0.004%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TRAVATAN (travoprost ophthalmic solution), 0.004%, 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 TRAVATAN (travoprost ophthalmic solution), 0.004%, 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. ANDAs that refer to TRAVATAN (travoprost ophthalmic solution), 0.004%, may 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0720]

International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports; Draft Guidance on Implementation; Data Elements and Message Specification; Appendix on Backwards and Forwards Compatibility; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Thursday, October 20, 2011 (76 FR 65199). The document announced the availability of a draft guidance entitled "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification" (the draft E2B(R3) implementation guidance) and an appendix to the draft guidance entitled "ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility" (the draft BFC appendix). The document was published with an incorrect date in the **DATES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993-0002, (301) 796-3601.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011-27147, appearing on page 65199