

## 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#### Determination That TRAVATAN (Travoprost Ophthalmic Solution), 0.004%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that TRAVATAN (travoprost ophthalmic solution), 0.004%, was not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.*

[FR Doc. 2011-29484 Filed 11-15-11; 8:45 am]

**BILLING CODE 4160-01-P**

## 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

in the **Federal Register** of Thursday, October 20, 2011, the following correction is made:

1. On page 65199, in the first column, in the **DATES** section, the date "January 18, 2011" is corrected to read "January 18, 2012."

Dated: November 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29485 Filed 11-15-11; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Neurological Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 10, 2012, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington, DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is (301) 977-8900.

*Contact Person:* Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993-0002, [Avena.Russell@fda.hhs.gov](mailto:Avena.Russell@fda.hhs.gov), (301) 796-3805, or FDA Advisory Committee Information Line, 1-(800) 741-8138, (301) 443-0572 in the Washington, DC area, and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the

appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On February 10, 2012, the committee will discuss and make recommendations regarding the possible reclassification of cranial electrotherapy stimulator (CES) devices. On August 8, 2011 (76 FR 48062), FDA issued a proposed rule which, if made final, would make CES devices Class III requiring premarket approval. In response to the proposed rule, FDA received petitions under section 515(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)(2)(B)) requesting a change in classification. The reclassification petitions are available for public review and comment at <http://www.regulations.gov> under docket number FDA-2011-N-0504. The committee discussion will include the existing data to support CES safety and effectiveness and whether the data are sufficient to develop special controls to support regulation of these devices under Class II.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 6, 2012. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 27, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the

speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 30, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov) or (301) 796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29528 Filed 11-15-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0599]

#### Center for Biologics Evaluation and Research Report of Scientific and Medical Literature and Information on Non-Standardized Allergenic Extracts in the Diagnosis and Treatment of Allergic Disease; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to April 25, 2012, the comment period for the notice on its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease that appeared in the **Federal Register** of September 26, 2011 (76 FR 59407). In the notice, FDA requested comments from public and private stakeholders on