

ECDD at its 37th meeting recommended that MXE be placed in Schedule II of the Psychotropic Convention. MXE is not currently controlled under the CSA in the United States. Additional controls will be necessary to fulfill U.S. obligations if MXE is controlled under Schedule II of the Psychotropic Convention.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2015.

Comments regarding the WHO recommendations for control of acetylfentanyl and MT-45 under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

IV. Opportunity for Public Meeting

FDA does not presently plan to hold a public meeting. If any person believes that, in addition to written comments, a public meeting would contribute to the development of the U.S. position on the substances to be considered for control under the Psychotropic Convention, a request for a public meeting and the reasons for such a request should be sent to James R. Hunter (see **FOR FURTHER INFORMATION CONTACT**) on or before February 5, 2016.

Dated: January 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01474 Filed 1-25-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-P-3053]

Determination That IZBA (Travoprost Ophthalmic Solution), 0.003 Percent, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA or Agency) has determined that IZBA (travoprost ophthalmic solution), 0.003 percent, was not withdrawn from sale for reasons of safety or effectiveness.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/drops, 0.003 percent, if all other legal and regulatory requirements are met.

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 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.

IZBA (travoprost ophthalmic solution), 0.003 percent, is the subject of

NDA 204822, held by Alcon Laboratories, Inc., and initially approved on May 15, 2014. IZBA is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

In a letter dated September 4, 2015, Alcon Laboratories, Inc. notified FDA that IZBA (travoprost ophthalmic solution), 0.003 percent, was discontinued. IZBA (travoprost ophthalmic solution), 0.003 percent, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Jonathan Goodman of Florek & Endres PLLC submitted a citizen petition dated August 20, 2015 (Docket No. FDA-2015-P-3053), under 21 CFR 10.30, requesting that the Agency determine whether IZBA (travoprost ophthalmic solution), 0.003 percent, was 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 IZBA (travoprost ophthalmic solution), 0.003 percent, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that IZBA (travoprost ophthalmic solution), 0.003 percent, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of IZBA (travoprost ophthalmic solution), 0.003 percent, 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 IZBA (travoprost ophthalmic solution), 0.003 percent, 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 IZBA (travoprost ophthalmic solution), 0.003 percent, 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: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Request for Nominations on the National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) for the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on the NMQAAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by *February 25, 2016*, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by February 25, 2016.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring,

MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT:

Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5215, Silver Spring, MD 20993. 301-796-5960, FAX: 301-847-8505, email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency request nominations for nonvoting industry representatives to the following committee:

I. National Mammography Quality Assurance Advisory Committee

The Committee shall advise the Food and Drug Administration on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a

candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the mammography manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Food and Drug Administration/Xavier University PharmaLink Conference: Increasing Product Confidence

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier