

For those unable to attend in person, the meeting will also be Webcast. The Webcast will be available at the following link: <https://collaboration.fda.gov/entdevices>.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301-796-5290, Natasha.Facey@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 8, 2013, the committee will discuss, make recommendations, and vote on information regarding the premarket approval (PMA) application for the Nucleus® Hybrid™ L24 Implant System sponsored by Cochlear Americas. The proposed Indications for Use for the Nucleus® Hybrid™ L24 Implant System (as stated in the PMA) is as follows:

The Nucleus® Hybrid™ L24 Implant System is intended for patients aged 18 years and older who have residual low-frequency hearing sensitivity and bilateral severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from bilateral hearing aids.

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 meeting 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 October 31, 2013. Oral presentations from the public will

be scheduled between approximately 1 p.m. and 2 p.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 October 22, 2013. 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 October 24, 2013.

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 AnnMarie Williams at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting. Requests for sign language interpretation or Communication Access Realtime Translation (CART)/captioning must be made 2 weeks in advance of the meeting, no later than October 25, 2013.

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: October 18, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1137]

GlaxoSmithKline LLC; Withdrawal of Approval of the Indication for Treatment of Patients With Relapsed or Refractory, Low Grade, Follicular, or Transformed CD20 Positive Non-Hodgkin's Lymphoma Who Have Not Received Prior Rituximab; BEXXAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the indication for treatment of patients with relapsed or refractory, low grade, follicular, or transformed CD20 positive non-Hodgkin's lymphoma who have not received prior rituximab, for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection held by GlaxoSmithKline LLP, P.O. Box 5089, 1250 South Collegeville Rd., Collegeville, PA 19426 (Glaxo). Glaxo has voluntarily requested that approval of this indication be withdrawn and has waived its opportunity for a hearing.

DATES: Effective October 23, 2013.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA approved BEXXAR on June 27, 2003, for the treatment of patients with CD20 positive, relapsed or refractory, low-grade, follicular, or transformed non-Hodgkin's lymphoma who have progressed during or after rituximab therapy. On December 22, 2004, FDA approved a new indication to include patients who have not received prior rituximab (the rituximab-naïve indication) under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E.

On December 13, 2011, FDA requested that Glaxo voluntarily withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection because the postmarketing study intended to verify clinical benefit and required as a condition of approval under part 601, subpart E was not completed. Withdrawal of approval of the rituximab-naïve indication does not otherwise affect the approved indication for BEXXAR.

On April 23, 2012, Glaxo submitted a prior approval labeling supplement requesting removal of the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection from the package insert. In the cover letter accompanying the supplement, Glaxo requested that FDA withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection from the market and waived its opportunity for a hearing. In a letter dated May 11, 2012, FDA acknowledged receipt of the prior approval labeling supplement and Glaxo's request to withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection. Glaxo's labeling supplement was approved by FDA in a letter dated August 15, 2012. Therefore, under section 506 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 356) and § 601.43, and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection is withdrawn as of October 23, 2013.

Dated: October 18, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-0665]

Determination That INTAL (cromolyn sodium) Inhalation Capsule, 20 Milligrams, 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 INTAL (cromolyn sodium) Inhalation Capsule, 20 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cromolyn sodium inhalation capsule, 20 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3602.

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.

INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, is the subject of NDA 16-990, held by Rhône-Poulenc Rorer Pharmaceuticals, Inc., and initially approved on June 20, 1973. INTAL is indicated for management of patients with bronchial asthma.

In a letter dated August 16, 1999, Rhône-Poulenc Rorer Pharmaceuticals, Inc., notified FDA that INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, had been discontinued in 1995 and requested withdrawal of NDA 16-

990 for INTAL. In the **Federal Register** of March 20, 2000 (65 FR 14983), FDA announced that it was withdrawing approval of NDA 16-990, effective April 19, 2000.

Alan G. Minsk and Kelley C. Nduom submitted a citizen petition dated May 23, 2013 (Docket No. FDA-2013-P-0665), under 21 CFR 10.30, requesting that the Agency determine whether INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, 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 INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of this product 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 INTAL (cromolyn sodium) Inhalation Capsule, 20 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. ANDAs that refer to INTAL (cromolyn sodium) Inhalation Capsule, 20 mg, 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: October 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-24783 Filed 10-22-13; 8:45 am]

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