

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Research, approval of the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection is withdrawn as of October 23, 2013.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#### **Determination That INTAL (cromolyn sodium) Inhalation Capsule, 20 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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Drug Administration (FDA) has determined that INTAL (cromolyn sodium) Inhalation Capsule, 20 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness.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.*

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