



NDA 21-375

Whitehall-Robbins
Five Giralda Farms
Madison, NJ 07940

Attention: David Smith, Ph.D.
Director, Regulatory Affairs

Dear Dr. Smith:

Please refer to your new drug application (NDA) dated August 23, 2001, received September 4, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Alavert (loratadine) Orally Disintegrating Tablets.

We acknowledge receipt of your submissions dated January 11, 17, and 22, February 4, 7, and 21(2), March 8, May 3, 13, 23, 24, and 31, June 28, July 11 and 19, September 5, October 14 and 31, and November 6 and 22, 2002. Your submission of October 14, 2002, constituted a complete response to our September 18, 2002, action letter.

This NDA provides for the over-the-counter use of Alavert (loratadine) Orally Disintegrating Tablets for the temporary relief of symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat.

We completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon labeling submitted October 14, 2002. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you based your application is subject to a period of patent protection and therefore final approval of your application under section 505(c)(3) of the Act (21 U.S.C. 355(c)(3)) may not be made effective until the period has expired, i.e., December 19, 2002.

Prior to December 19, 2002, or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Consider amending your NDA prior to December 19, 2002, with updated labeling that reflects the advice provided in comment 2.b. of our October 28, 2002, facsimile correspondence. Otherwise, after

you receive final approval implement this change in your labeling in the next printing or within 6 months, whichever is sooner.

We remind you of your post-approval follow-up agreement in your submission dated November 13, 2002, to submit information in each quarterly periodic safety report for the first three years after approval on reports from various sources of the occurrence of hypospadias.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letters before December 19, 2002, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before final approval.

If you have any questions, call Anthony M. Zeccola, Regulatory Management Officer, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

{See appended electronic signature page}

Badrul Chowdhury, M.D., Ph.D.
Acting Director
Division of Pulmonary and Allergy
Drug Products
Center for Drug Evaluation and Research

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/s/

Charles Ganley
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Badrul Chowdhury
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