CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-512

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-512

Perrigo
515 Eastern Avenue
Allegan, Michigan 49010

Attention: Janette J. Meyer

Dear Ms. Meyer,

Please refer to your new drug application (NDA) dated June 28, 2002, received July 1, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for loratadine 10mg tablets.

We also refer to your amendments dated December 18, 2002, January 22, February 18, March 4 (2), 5, 12, and 18, April 11, May 9, 12, and 23, June 18, 23, and 27, July 1, and December 22, 2003, April 29 and May 4, 2004.

Your submission of December 22, 2003, received December 24, 2003, constituted a complete response to our July 11, 2003, action letter.

This new drug application provides for the over-the-counter use of loratadine 10 mg 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 approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

While the re-assay of samples has been deemed to be adequate in establishing the quality and reliability of the submitted data, the source of contamination in the original assay has not been identified although efforts have been made to address this issue in the modified assay used for the reanalysis of the samples. We recommend that for future submissions where contaminations are observed during analysis, the source(s) of the contamination should be identified before they are addressed by a new or modified assay method.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container, carton labels and blister backing submitted April 29, 2004), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format (pdf) effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in*

Electronic Format – Content of Labeling (February 2004). The guidances specify that the labeling content must be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

If you choose to market this product using a proprietary name, the name must first be approved via submission of a prior approval supplement. The name and its presentation in labeling must also conform to the specifications under 21 CFR 201.10, 201.15, 201.60, and 201.61. If you are distributing this product only through other companies, submit a list of the distributors/repackers and corresponding proprietary names in each annual report.

We remind you of your post-approval follow-up agreements in your submissions dated June 18 and May 4, 2004. These include an agreement to submit a prior approval supplement for any new proprietary name and submitting information in each quarterly periodic safety report for three years after approval on reports from various sources of the occurrence of cases of hypospadias.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, call Elaine Abraham, Regulatory Management Officer, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

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

Sincerely,

{See appended electronic signature page}

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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
6/24/04 02:46:05 PM

Charles Ganley
6/24/04 04:03:18 PM