CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-734

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-734

Taro Pharmaceuticals, U.S.A., Inc.
5 Skyline Drive
Hawthorne, NY 10532

Attention: Kalpana Rao
Vice President, Regulatory Affairs

Dear Ms Rao:

Please refer to your new drug application (NDA) dated January 19, 2004, received January 21, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Loratadine Oral Suspension, 5mg/5mL.

We acknowledge receipt of your submissions dated May 6, August 4, and 26, and September 2, and 16, 2004, and April 1, May 5, July 12, August 22, and 30, September 2, 14, and 27, and October 2, 2005.

The submission dated April 1, 2005, received April 4, 2005, constituted a complete response to our November 19, 2004, action letter.

This new drug application provides for the use of Loratadine Oral Suspension as follows, "temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: Runny nose, sneezing, itchy, watery eyes, itching of the throat or nose."

We have 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 and with the minor editorial revision listed below, as agreed upon in our October 3, 2005, telephone conversation,:

Remove "Children's" from the established name and from appearing in the Principle Display Panel (PDP).

The final printed labeling (FPL) must be identical to, except for including the revisions listed above, the immediate container and carton labels submitted September 2, 2005, and must be in the "Drug Facts" format (21 CFR 201.66). These revisions are terms of the NDA approval. Marketing the product(s) before making the revisions, exactly as stated, in the product's labeling and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies

of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-734**." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 Office or Nonprescription Products.

If you have any questions, call Elaine Abraham, Regulatory Management Officer, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription 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: Labeling