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RESEARCH**

APPLICATION NUMBER:

21-891

APPROVAL LETTER



NDA 21-891

Schering-Plough HealthCare Products
Attention: Doreen Frank
Director, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901-1330

Dear Ms. Frank:

Please refer to your new drug application (NDA) dated August 2, 2005, received August 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Claritin (loratadine) Chewable Tablets 5 mg.

We acknowledge receipt of your submissions dated June 23 and 26, 2006.

The June 26, 2006 submission constituted a complete response to our June 1, 2006 action letter.

This new drug application provides for the use of Children's Claritin (loratadine) Chewable Tablets 5 mg for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (sachet and carton labeling, bi-fold card and sample tray labeling submitted March 30, 2006, and blister packages submitted August 2, 2005), 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.

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 21-891.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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

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

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.

Director

Division of Nonprescription Clinical Evaluation

Office of Nonprescription Products

Center for Drug Evaluation and Research

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

/s/

Andrea Segal

8/23/2006 11:21:42 AM