



NDA 20-641/S-025

Schering-Plough HealthCare Products, Inc.
Attention: Nancy Pierro
Senior Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Ms. Pierro:

Please refer to your supplemental new drug application dated April 29, 2008, received April 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin Oral Solution (loratadine 5mg/5mL syrup).

We acknowledge receipt of your submissions dated June 3, 12 and July 24, 2008.

This supplemental new drug application provides for the addition of the descriptor "Indoor & Outdoor Allergies" to the principal display panel for Claritin® Oral Solution, both the Original Fruit Flavor and the Grape Flavor. This labeling supersedes the labeling submitted in Supplement 024 for the Original Fruit Flavor and includes the changes to the labeling under that supplement for a new plastic bottle container/closure system for the Original Fruit Flavor only. Refer to our letter dated July 25, 2008.

We have completed our review of this application, as amended. This supplement is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. Revise the tamper-evident statement on the Grape Flavor carton and container labels to include an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture) in accordance with the regulation (21 CFR 211.132(b)(1), and include the identifying characteristic in the tamper-evident feature.

You should revise the carton and container labels with the above requested revision at the time of next printing, or within 180 days, whichever come first. The revised labels can be submitted in the next annual report.

In your letter of July 24, 2008, you committed to adding dosing directions to the container labels for both the Grape Flavor and Original Fruit Flavor oral solutions to include directions for children under 2 years of age. Under Directions, the statement "children under 2 years of age:" is followed by "ask a doctor" on the carton label and "■■■■ a doctor" on the mock-up container label. The language should be consistent on the carton and container.

The final printed labeling (FPL) must be identical to, and include the revisions listed, the submitted labeling (4 fl. oz. carton labels submitted April 29, 2008 and 4 fl. oz. container labels with commitment submitted July 24, 2008), and must be formatted in accordance with the applicable requirements of 21 CFR 201.66. These revisions are terms of the approval of this application. We understand that the 4 fl. oz size will be the only marketed SKU for this product.

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 supplement NDA 20-641/S-025.**” Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the 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}

Joel Schiffenbauer, M.D.
Deputy 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
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/s/

Joel Schiffenbauer
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