DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-641/S-018

Schering-Plough HealthCare Products
Attention: Mary Williams
Associate Director, Regulatory Affairs
Three Connell Drive
Berkeley Heights, NJ 07922

Dear Ms. Williams:

Please refer to your supplemental new drug application dated February 28, 2005, received March 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (loratadine oral solution 5mg/5mL) Syrup.

We also refer to your amendments dated March 21, April 13, and May 11 and 25, 2005.

This supplemental new drug application proposes a new grape flavored formula, a new manufacturing site, new packaging, and new analytical methods and specifications.

We have completed our review of this supplemental new drug application, as amended. This supplement 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 submitted draft labeling (2 and 4 fl. oz. carton and container labels submitted April 13, 2005) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-641/S-018." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the word "NEW" in the flag "NEW! Grape Flavor" from the principal display panel after 180 days of marketing.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Acting 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/

Curtis Rosebraugh
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