DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-641/S-017

Schering Corporation
Attention: Joyce Yates
Associate Director, Regulatory Affairs
2000 Galloping Hill
Kenilworth, New Jersey 07033

Dear Ms. Yates:

Please refer to your supplemental new drug application dated April 27, 2004, received April 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (loratadine) Syrup, 1mg/ml.

We also refer to your amendment dated September 23, 2004.

This "Changes Being Effected" supplemental new drug application provides for updating the deliverable volume acceptance criteria for the drug product to meet the labeling claim of 120 mL for the 4 oz. bottle.

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 (carton and container labels submitted September 23, 2004) 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-017." Approval of this submission by FDA is not required before the labeling is used.

We have the following additional recommendation for implementation prior to your next printing:

> The print used for the asterisked statement at the bottom of the PDP, "When taken as directed. See Drug Facts Panel" should be changed back to the original or another conspicuous print that is easier to read. This change can be made at the time of the next printing or within 180 days, whichever comes first. The change can be submitted in the next annual report.

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.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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

10/27/04 11:55:42 AM