DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-658/S-020
NDA 20-704/S-009
NDA 20-641/S-011

Schering Corporation
Attention: Joseph F. Lamendola, Ph.D.
Vice President, Worldwide Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Lamendola:

Please refer to your supplemental new drug applications dated January 25, 2002, received January 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (10 mg loratadine) Tablets, Reditabs, and Claritin (5 mg/5 mL loratadine) Syrup.

We acknowledge receipt of your submissions dated March 22 and 28 (2), and August 9, 2002, and May 16, November 12, 13, and 17, 2003. Your May 16, 2003, submission constituted a complete response to our November 27, 2002, action letter.

These supplemental new drug applications provide for the over-the-counter use of Claritin (loratadine) Tablets, Reditabs, and Syrup for the relief of itching due to hives (urticaria) to be marketed under the tradename, Claritin Hives Relief.

We have completed our review of these supplemental applications, as amended, and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (carton and container labels and blister cards submitted November 12, 2003, and package insert submitted November 17, 2003). 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-658/S-020, 20-704/S-011, and 20-641/S-009." Approval of these submissions by FDA is not required before the labeling is used.

In addition, we recommend, for all products, that you revise the bulleted statement "an allergic reaction to this product occurs. Get medical help right away." to appear in regular (unbolded) type under the "**Stop use and ask a doctor if**" section of the "Drug Facts" labeling.

We remind you to remove the word "NEW!" on the principal display panel (PDP) 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 (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Badrul Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug 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/

Badrul Chowdhury
11/19/03 12:44:46 PM

Curtis Rosebraugh
11/19/03 01:21:37 PM