DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-670/S-018
NDA 20-470/S-016

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Joseph F Lamendola, Ph.D.
Vice President, U.S. Regulatory Affairs

Dear Dr. Lamendola:

Please refer to your supplemental new drug applications (NDAs) dated January 25, 2002, received January 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin® (loratadine/pseudoephedrine sulfate) D-12 and D-24 Extended Release Tablets.

We acknowledge receipt of your submissions dated February 12, March 22 and 28 (2), July 2, August 9 (2), September 6, 16, and 25, October 24, and November 12, 13, and 15, 2002.

These supplemental new drug applications provide for the over-the-counter use of Claritin (loratadine/pseudoephedrine sulfate) D-12 and D-24 Extended Release for the temporary relief of symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy, watery eyes, itching of the nose or throat; temporary reduction of swelling of nasal passages; temporary relief of sinus pressure; and temporary restoration of freer breathing through the nose.

We have completed our review of these supplemental applications as amended. These supplemental applications are 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 labels and blister back submitted November 12, 2002), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the products with FPL that is not identical to the approved labeling text and in the required format may render the products misbranded and unapproved new drugs.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved NDAs 19-670/S-018 and 20-470/S-016**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your post-approval follow-up agreement in your submission dated November 13, 2002, to submit information in each quarterly periodic safety report for the first three years after approval on reports from various sources of the occurrence of cases of hypospadias.

Oversight of this applications is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, call Elaine Abraham, R.Ph., Regulatory Management Officer (HFD-560), at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Robert Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Jonca Bull
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