DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-670/S-019
NDA 20-470/S-022

Schering-Plough HealthCare Products
Attention: John M. Clayton, Ph.D.
Senior Vice President, Scientific and Regulatory Affairs
3 Connell Drive
Berkeley Heights, NJ 07922-0603

Dear Dr. Clayton:

Please refer to your supplemental new drug applications dated March 9, 2004, received March 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin-D 12 Hour and Claritin-D 24 Hour (loratadine and pseudoephedrine sulfate) Extended Release Tablets, 5mg/120mg and 10mg/240mg.

We acknowledge receipt of your submissions dated May 6, 2004.

These supplemental new drug applications provide for the use of Claritin-D in the temporary relief of nasal congestion due to the common cold in adults and children 12 years and older.

We completed our review of these supplemental applications, as amended. These supplements 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 submitted March 9, 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, these submissions should be designated "FPL for approved supplement NDA 19-670/S-019 and 20-470/S-022." Approval of these submissions by FDA is not required before the labeling is used.

We remind you to remove the phrase "See New Use" on the PDP after 180 days of marketing.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are

waiving the pediatric study requirement for ages birth to 12 years for this application.

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, R.Ph., 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
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