DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-453/S-014

Schering-Plough HealthCare Products
Attention: John M. Clayton, Ph.D.
Senior Vice President Scientific & Regulatory Affairs
3 Oak Way
Berkeley Heights, NJ 07922

Dear Dr. Clayton:

Please refer to your supplemental new drug application dated September 30, 2002, received October 01, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Drixoral Cold & Flu Extended Release and Drixoral Allergy Sinus (60 mg pseudoephedrine sulfate, 500 mg acetaminophen, and 3 mg dexbrompheneramine maleate) Extended Release Tablet.

This supplemental new drug application provides for revisions to the Drug Facts labeling, including changes to the active ingredients and warnings section.

We have completed our review of this application, and it 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 labeling (carton labels submitted September 30, 2002), 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-453/S-014." Approval of this submission by FDA is not required before the labeling is used.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on specific warnings in the future.

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 reporting 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}

Curtis Rosebraugh, M.D.
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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