DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-483/S-042

Schering-Plough HealthCare Products
Attention: Joyce Yates
Associate Director, Regulatory Affairs
3 Connell Drive
P.O. Box 603
Berkeley Heights, NJ 07922-0603

Dear Ms. Yates:

Please refer to your supplemental new drug application dated November 9, 2004, received November 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Drixoral® Cold & Allergy (6 mg dexbrompheniramine maleate and 120 mg pseudoephedrine sulfate) extended release tablets.

This supplemental new drug application provides for the following:

- product reformulation
- new manufacturing process
- new manufacturing site
- new analytical procedures and acceptance criteria.

We have completed our review of this supplemental application. 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 draft labeling (carton and blister card labels submitted on November 9, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 13-483/S-042**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag “See label for new inactive ingredients” from the principal display panel 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) 827-2276.

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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