DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-506/S-024

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 application dated April 12, 2002, received April 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trinalin Repetabs (1 mg azatadine maleate/ 120 mg pseudoephedrine sulfate tablets).

We acknowledge receipt of your submission dated September 13, and November 21, 2001.

Your submission of November 21, 2001, constituted a complete response to our October 21, 2001 action letter.

This supplemental new drug application provide for the addition of a Geriatric Use subsection to the WARNING section, modification of the statement regarding patients receiving monoamine oxidase (MAO) inhibitors in the CONTRAINDICATIONS section and Information for Patients subsection of the PRECAUTIONS section and deletion of the reference to oral anticoagulants in the WARNINGS section and Information for Patients subsection of the PRECAUTIONS section of the package insert.

We completed our review of this application, as amended. This application 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 (package insert submitted November 21, 2001).

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 18-506/S-024." Approval of this submission by FDA is not required before the labeling is used.

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 Ms. Colette Jackson, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Acting Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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
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