DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 7-638/S-032

Schering-Plough HealthCare Products
Attention: Joyce Yates
Associate Director, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901-1330

Dear Ms. Yates:

Please refer to your supplemental new drug application dated September 16, 2005, received September 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chlor-Trimeton Allergy (12 mg chlorpheniramine maleate) tablets.

We acknowledge receipt of your submission dated September 23, 2005.

This supplemental new drug application provides for a product reformulation, revised product labeling, a new manufacturing process, a new manufacturing site, and new analytical specifications and methods.

We have completed our review of this application, as amended. 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 (package labeling submitted September 16, 2005), 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 7-638/S-032**." 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
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Susan Johnson, Ph.D.
Associate Director
Office of Nonprescription Products
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/

Susan Johnson
1/19/2006 12:20:44 PM