**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-381/S-026 and S-027

Wyeth-Ayerst Research
P.O. Box 8299
Philadelphia PA 19101-8299

Attention: Tracy Rockney, J.D.
Director, Global Brand Management
Worldwide Regulatory Affairs

Dear Dr. Rockney:

Please refer to your supplemental new drug applications dated August 3 and 13, 2001, received August 6 and 16, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phenergan (promethaszine HCl) Syrup and Fortis.

These supplemental new drug applications provide for the following revisions to the package insert:

S-026 - Revisions to the package insert in the CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION and HOW SUPPLIED sections.

S-027 - The addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert.

We completed our review of S-027 and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. With the approval of supplemental application S-027, supplemental application S-026 is superceded, therefore, we will not review this supplemental application but it will be retained in our files.

The final printed labeling (FPL) must be identical to the labeling text for the package insert, submitted August 13, 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 8-381/S-027." 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) 827-5584.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Badrul Chowdhury
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