DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-689/S-016, S-018, S-019, and S-020

Wyeth-Ayerst Laboratories
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 December 6, 2000, and July 6, and 12, and August 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pherengan (promethazine HCl) Suppositories, 50 mg.

We acknowledge receipt of your submission dated December 14, 2001, to S-020.

These supplemental new drug applications provide for:

S-016 - revisions to the package insert in the DESCRIPTION, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, and DOSAGE AND ADMINISTRATION sections.

S-018 - revision to the package insert in the CLININCAL PHARMACOLOGY, CONTRAINDICATIONS, PRECAUTIONS/General, Information for Patients, Drug Interactions, Use in Geriatric Patients, ADVERSE REACTIONS/Central Nervous System, Other, Paradoxical Reactions, and OVERDOSAGE sections along with formatting changes throughout.

S-019 - revisions to the package insert in the CLINICAL PHARMACOLOGY, CONTRAINDICTIONS, WARNINGS/CNS Depression, Lower Seizure Threshold, Use in Pediatric Patients, PRECAUTIONS/General, Information for Patients, Drug Interactions, Pregnancy, ADVERSE REACTIONS/Central Nervous System, Paradoxical Reactions, and OVERDOSAGE sections.

S-020 - the addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert.

We completed our review of supplemental application S-020 and have concluded that adequate information has been submitted to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, supplemental application S-020 is approved. With the approval of supplemental application S-020, supplemental applications S-016, S-

018 and S-019 are superceded, therefore, we will not review these supplemental applications but they will be retained in our files.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 14, 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 11-689/S-020. 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, M.D., Ph.D.
Acting Director
Division of Pulmonary and Allergy Drug Product
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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