DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-689/S-024

Wyeth Pharmaceuticals
P.O. Box 8299
Philadelphia, PA 19101-8299

Attention: David Ellis, Ph.D.
Senior Director
Worldwide Regulatory Affairs

Dear Dr. Ellis:

Please refer to your supplemental new drug application dated May 6, 2004, received May 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phenergan (promethazine HCl) Suppositories, 50mg.

We acknowledge receipt of your submission dated July 23, 2004.

This supplemental new drug application provides for labeling changes to the **WARNINGS**, **WARNINGS/Use in Pediatric Patients**, and **DOSAGE AND ADMINSTRATION** sections of the package insert for Phenergan Tablets and Suppositories.

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 enclosed labeling.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 11-689/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, HFD-410
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 Lori Garcia, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products, HFD-570
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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
11/8/04 09:02:46 AM