



NDA 11-265/S-028

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

Attention: Tracy Rockney
Director
Worldwide Regulatory Affairs

Dear Ms. Rockney:

Please refer to your supplemental new drug application dated July 17, 2003, received July 18, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phenergan with dextromethorphan (promethazine HCl and dextromethorphan hydrobromide) Syrup.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert as follows:

1. Revisions to the DESCRIPTION section to modify the solubility statement.
2. Revisions to the Labor and Delivery subsection of the PRECAUTIONS section to include descriptive information.
3. Revisions to the HOW SUPPLIED section to reflect the current definition of Controlled Room Temperature.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 17, 2003.

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 the requirements for an approved NDA set forth under 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
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Badrul Chowdhury
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