DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-026/S-024

Wyeth Pharmaceuticals, Inc.
Attention: Mr. Randall B. Brenner
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Brenner:

Please refer to your supplemental new drug application, dated December 22, 2005 and received December 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement Number
Trecator® (ethionamide) Tablets, 250 mg	13-026	S-024

This "Changes Being Effected" supplemental new drug application provides for the following addition of hypothyroidism to the **ADVERSE REACTIONS** section of the text for the package insert (double-underlined = added text):

- The **ADVERSE REACTIONS** section of the package insert was revised as follows:

  Other: Hypersensitivity reactions including rash, photosensitivity, thrombocytopenia and purpura have been reported rarely. Hypoglycemia, hypothyroidism, gynecomastia, impotence, and acne also have occurred. The management of patients with diabetes mellitus may become more difficult in those receiving ethionamide.

We completed our review of this application. 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 (text for the package insert).

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 13-026/S-024**." Approval of this submission by FDA is not required before the labeling is used.

The electronic labeling rule published December 11, 2003 (FR 69009) requires submission of content of labeling [21 CFR 201.100(d)(3)] in electronic format effective June 8, 2004. For additional information, consult the guidance for industry *Providing Regulatory Submissions in Electronic Format*

- *Content of Labeling* (April 2005). The guidance specifies that, as of fall 2005, content of labeling is to be submitted in structured product labeling (SPL) format. To facilitate our review of your submission, we ask that labeling also be submitted in MS Word format with proposed revisions clearly indicated.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Rebecca Saville, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
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/

Renata Albrecht

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