DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 8-085/S-053/S-054
NDA 11-719/S-102/S-103

Wyeth-Ayerst Laboratories
Attention: Timothy Ressler
Director, Global Brand Management
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Ressler:

Please refer to your supplemental new drug applications dated October 5, 2001, received October 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methotrexate Sodium Tablets, Methotrexate Sodium for Injection and Methotrexate Sodium Injection.

The supplements provide FPL for approved supplements NDA 8-085/S-046 and S-051 as well as NDA 11-719/S-096 and S-100. In addition, the supplements 8-085/S-054 and 11-719/S-103 provide safety related changes under 21 CFR 314.70 (c)(i).

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (revised May 9, 2001 package insert CI 4436-6 version for NDA 8-085 and revised 05/2001 package insert CI 4814-7 version for NDA 11-719 submitted October 5, 2001). Accordingly, these supplemental applications (S-054/S-103) are approved effective on the date of this letter.

We also note that your additional supplemental applications (8-085/S-053 and 11-719/S-102) submitted on May 23, 2001 have been superseded by supplemental applications 8-085/S-054 and 11-719/S-103. Therefore, we will not review these supplemental applications but they will be retained in our files.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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