NDA 17-007/S-038

SEP 6 2000

Wyeth-Ayerst Laboratories
Attention: Ms. Mary Alice Dankulich
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Dankulich:

Please refer to your supplemental new drug application dated August 10, 1998, received August 11, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Injection, USP; Heparin Lock Flush Solution, USP; and Heparin Flush Kits (Heparin Lock Flush Solution, USP and Bacteriostatic Sodium Chloride Injection, USP).

We also refer to your submission dated December 29, 1998, received December 30, 1998, submitted in response to the Agency's September 15, 1998 refuse-to-file letter.

We acknowledge receipt of your submission dated August 3, 2000. That submission constituted a complete response to our July 16, 1999 action letter.

This supplement new drug application provides for the following: (1) in the PRECAUTIONS section, the addition of a "Geriatric Use" subsection, to the package insert in response to the Final Rule entitled "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use' Subsection in the Labeling," published in the August 27, 1997 Federal Register (62 FR 45313-45326); (2) in the PRECAUTONS section, the "General" subsection, the deletion of the "*Increased Risk in Older Women*" sub-subsection of the "Heparin Lock Flush Solution, USP" and the "Heparin Sodium Injection, USP" package inserts; (3) deletion of the statement "Caution: Federal law prohibits dispensing without prescription."; and (4) insertion of the phrase "R_x only" below the title section of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in final printed labeling for the Heparin Sodium Injection, USP and the Heparin Lock Flush Solution, USP package inserts, submitted August 3, 2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

We note that the Heparin Flush Kits have been discontinued, and, therefore, the final printed labeling for the Heparin Flush Kits package insert was not included in the August 3, 2000 submission.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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 Karen Oliver, Regulatory Health Project Manager, at (301) 827-7457.

Sincerely,

9-6-00

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research