DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-029/S-099

American Pharmaceutical Partners, Inc.
Attention: Ms. Genny Cruz
Senior Regulatory Scientist
2045 North Cornell Avenue
Melrose Park, IL 60160-1002

Dear Ms. Cruz:

Please refer to your supplemental new drug application dated October 3, 2001, received October 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Injection, USP and Heparin Lock Flush Solution, USP.

This "Changes Being Effected" supplemental new drug application provides final printed labeling (FPL) in response to FDA's *Guidance for Industry: Revising ANDA Labeling Following Revision of the Reference-Listed Drug (RLD) Labeling* issued May 2000. The package insert for **HEPARIN LOCK FLUSH SOLUTION, USP**, has been revised in accordance with the changes noted in the reference-listed drug's (Wyeth-Ayerst NDA 17-007) labeling for Heparin Lock Flush Solution, USP obtained from the FDA's MedWatch, CDER Labeling Review Branch websites, as well as the updates made in the reference-listed drug's (Wyeth-Ayerst) labeling.

We have completed the review of this supplemental application 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 (package insert submitted October 3, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

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 Cheryl Perry, Regulatory Health Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick

3/22/02 04:12:17 PM