DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-029/S-108

APP Pharmaceuticals, LLC
Attention: Aditi Dron
Regulatory Scientist
1501 East Woodfield Road, Suite 300E
Schaumburg, IL 60173

Dear Ms. Dron:

Please refer to your supplemental new drug application dated November 30, 2007, received December 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Injection, USP.

We acknowledge receipt of your submissions dated June 18, July 18 and September 2, 2008.

This "Changes Being Effected" supplemental new drug application provides for revised package insert to follow the transfer of the NDA to APP Pharmaceuticals from Abraxis Bioscience, Inc. and to fulfill the requests made by the Agency in the July 11, 2008 letter. This letter requested changes to the **WARNINGS** and **DOSAGE AND ADMINISTRATION** sections of the package insert in regard to heparin being marketed in a wide range of strengths, and that fatal medication errors have occurred due to confusion of vials, and that this risk is greatest in infants and neonates, and to include statements urging careful examination of the heparin product vial to ensure that the proper strength is selected for administration.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 2, 2008.

We note that carton and vial labeling are not included in the current supplement, therefore, aspects of the carton and vial labeling pertinent to the July 11, 2008 supplement request still need to be addressed. You should provide a timeline for your response.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: NDA 17-029/S-108 PI.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rafel Rieves

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