DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-651/S-042

Abraxis Pharmaceutical Products
Attention: Nicole M. Cage
Regulatory Scientist
6133 North River Road, Suite 500
Rosemont, IL 60018

Dear Ms. Cage:

Please refer to your supplemental new drug application dated June 15, 2007, received June 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium, Injection, USP (porcine) 5,000 U/mL.

We acknowledge receipt of your submission dated December 7, 2007.

This "Changes Being Effected" supplemental new drug application provide for revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the package insert to be more consistent with the current heparin class labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the package insert submitted on June 15, 2007 and the in the agreed-upon labeling text for the immediate container label.

The final printed labeling (FPL) for the immediate container label must be identical to the enclosed labeling (immediate container labels) and/or submitted labeling immediate container label submitted December 7, 2007).

Please submit an electronic version of the immediate container 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 17-651/S-042**." Approval of this submission by FDA is not required before the labeling is used.

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 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 17-651/S-042

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/s/

Rafel Rieves

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