CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-660/S-013

Trade Name: Abraxane

Generic Name: paclitaxel

Sponsor: Abraxis Bioscience, Inc.

Approval Date: July 1, 2008

Indications: For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.

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APPLICATION NUMBER:

NDA 21-660/S-013

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APPLICATION NUMBER:

NDA 21-660/S-013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-660/S013

Abraxis Bioscience, Inc.
Attention: Aleece C. Nolasco
Regulatory Scientist
4503 Glencoe Avenue
Marina Del Ray, CA 90292

Dear Ms. Nolasco:

Please refer to your supplemental new drug application S013, dated May 24, 2007 and received May 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abraxane® (paclitaxel) for injectable suspension.

We acknowledge receipt of your submission dated May 24, 2007 and to the related Addendum 1 to the Periodic Adverse Drug Experience Report 2007, dated May 24, 2007.

This "Changes Being Effected" supplemental new drug application provides for an addition to the ADVERSE EVENT EXPERIENCE BY BODY SYSTEM section of the labeling (package insert) with the following text:

> "During postmarketing surveillance, rare occurrences of severe hypersensitivity reactions have been reported with ABRAXANE. The use of ABRAXANE in patients previously exhibiting hypersensitivity to paclitaxel injection or human albumin has not been studied. Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with the drug."

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 enclosed agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated May 24, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 21-660/S013".**

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Carl Huntley, Regulatory Project Manager, at (301) 796-1372.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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