CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-660/S-022

Trade Name: Abraxane

Generic Name: paclitaxel

Sponsor: Abraxis Bioscience, Inc.

Approval Date: June 26, 2009

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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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-660/S-022

Abraxis BioScience, Inc.
Attention: Monica Batra
Sr. Regulatory Scientist
2730 Wilshire Blvd., Suite 500
Santa Monica, CA 90403

Dear Ms. Batra:

Please refer to your supplemental new drug application dated July 31, 2008, and received August 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin bound), 100 milligram vial.

We also acknowledge receipt of your submission dated May 29 and electronic mail correspondence of June 18, 2009.

This supplemental new drug application provides for the completed final report for CA037, *A Phase I Study to Evaluate the Safety and Pharmacokinetics of ABI-007 in Patients with Advanced Solid Tumors and Hepatic Dysfunction* to fulfill the January 7, 2005 postmarketing study commitment 2 with labeling changes to include dosing adjustments for hepatically impaired patients as well as additional labeling changes proposed for consistency with company's core data sheet and global 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 agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling (text for the package insert, text for the patient package insert). 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 NDA 21-660**."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Janet Jamison, Acting Safety Regulatory Project Manager, at (301) 796-2313.

Sincerely,

{See appended electronic signature page}

Robert Justice, MD, MS
Director
Division of Drug Oncology Products
Office of Oncology Products
Center for Drug Evaluation and Research

Enclosure:

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