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Approval Package for:

APPLICATION NUMBER:

NDA 21-660/S-010

Trade Name: Abraxane

Generic Name: paclitaxel

Sponsor: Abraxis BioScience, Inc.

Approval Date: February 15, 2007

Indications: For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

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NDA 21-660/S-010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-660/S-010

Abraxis BioScience, Inc.
Attention: Monica Batra
Manager, Regulatory Affairs
4503 Glencoe Ave.
Marina Del Rey, CA 90292

Dear Ms. Batra:

Please refer to your supplemental new drug application dated April 14, 2006, received April 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension).

We acknowledge receipt of your submissions dated June 14 and 29; July 21 and December 5, 2006; January 15; February 9 and 14 (electronic), 2007.

This supplemental new drug application provides revised prescribing information with updated safety and efficacy information for ABRAXANE® Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) in the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

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.

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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) for this supplement S-010 must be identical to the enclosed labeling (text for the package insert, and text for the patient package insert) submitted February 9, 2007. Please note that your final printed labeling submitted January 20, 2005, for this NDA has been superseded but will be retained in the file.

Please submit an electronic version of the 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 21-660/S-010." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated January 4, 2004.

2. You should evaluate ABRAXANE® safety and pharmacokinetics in subjects with hepatic impairment, to allow the determination of dosing adjustment for this population.

   Protocol Submission: April 2005
   Study Start: November/December 2005
   Final Report Submission: December 2006

Per your submission of December 5, 2006, we understand that the final report submission for this postmarketing study commitment will be delayed until November 2007. This is acceptable.

We have reviewed your submissions dated June 28 and August 12, 2005, and conclude that the following commitment from the January 7, 2005, approval letter was fulfilled.

1. Survival data and analysis results should be submitted from randomized study CA012-0 when 80% of the patients have died. Data should be available for submission approximately June 2005.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

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