DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021660/S-034
NDA 021660/S-035

SUPPLEMENT APPROVAL

Abraxis BioScience, LLC,
a wholly-owned subsidiary of Celgene Corporation
c/o Celgene Corporation
Attention: Renu Vaish, M.S.
Executive Director, Regulatory Affairs
400 Connell Drive, Suite 7000
Berkeley Heights, NJ 07922

Dear Ms. Vaish:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 24, 2012, received February 24, 2012, and May 30, 2012, received May 30, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abraxane for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), 100 milligram vial.

"Prior Approval" supplemental new drug application (S-034) provides for inclusion of pneumonitis under the subheading Respiratory in Section 6.2 Post Marketing Experience with Abraxane and other Paclitaxel Formulations, ADVERSE REACTIONS, and inclusion of fatal hypersensitivity as a new heading - 5.3 Hypersensitivity, WARNINGS AND PRECAUTIONS, of the Full Prescribing Information of the Package Insert. S-034 also provides for corresponding revisions to Section 17 Patient Counseling Information and Recent Major Changes of the Full Prescribing Information of the Package Insert, the Patient Package Insert and minor administrative, editorial and grammatical revisions throughout the Package Insert and Patient Package Insert.

"Prior Approval" supplemental new drug application (S-035) provides for inclusion of cystoid macular edema (CME) under the subheading Vision Disorder in Section 6.2 Post Marketing Experience with Abraxane and other Paclitaxel Formulations, ADVERSE REACTIONS, of the Full Prescribing Information of the Package Insert.

We acknowledge receipt of your amendments dated September 17, 2012, and September 27 (electronic mail), 2012.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

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You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Yolanda Adkins, Regulatory Project Manager, at (301) 796-2850.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Division Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AMNA IBRAHIM
09/28/2012