CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

021660Orig1s026

Trade Name:	ABRAXANE for Injectable Suspension
Generic or Proper Name:	paclitaxel protein-bound particles for injectable suspension (albumin-bound)
Sponsor:	Celgene Corporation
Approval Date:	December 23, 2011
Indication:	For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or replase within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

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021660Orig1s026

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APPLICATION NUMBER:

021660Orig1s026

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021660/S-025
NDA 021660/S-026
NDA 021660/S-029

SUPPLEMENT APPROVAL

Celgene Corporation
Attention: Renu Vaish, M.S.
Executive Director, Global Regulatory Affairs
Therapeutic Franchise Leader - Oncology Solid Tumors
400 Connell Drive, Suite 7000
Berkeley Heights, NJ 07922

Dear Ms. Vaish:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 30, 2010, received March 30, 2010, June 1, 2010, received June 2, 2010, and July 25, 2011, received July 25, 2011, 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.

We acknowledge receipt of your amendments dated December 8, 2010; February 25, 2011; July 8, 2011; August 26, 2011; August 30, 2011; September 1, 2011; September 6, 2011; September 8 (2), 2011; September 13, 2011; September 14, 2011; September 21, 2011, December 5, 2011; December 20, 2011, and December 22 (2), 2011.

“Prior Approval” supplemental new drug application (S-025) provides for inclusion of pyrexia, dehydration, pancytopenia, congestive heart failure, and left ventricular dysfunction in Section 6, ADVERSE REACTIONS of the Package Insert.

“Prior Approval” supplemental new drug application (S-026) provides for revised labeling in the Physican Labeling Rule format.

“Prior Approval” supplemental new drug application (S-029) provides for inclusion of three adverse events: Stevens-Johnson syndrome, toxic epidermal necrolysis and extravasation in Section 6, ADVERSE REACTIONS of the Package Insert and minor administrative, editorial and grammatical revisions throughout the Package Insert.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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)

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