DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-660

American BioScience, Inc.
Attention: Mitchall G. Clark
Vice President, Regulatory Affairs
2730 Wilshire Boulevard, Suite 110
Santa Monica, CA 90403

Dear Mr. Clark:

Please refer to your new drug application (NDA) dated March 4, 2004, received March 8, 2004, pursuant to section 505(b)(2) 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 30, July 21, and August 21, 2003; February 4 and 27; March 4, 15, 18, and 19; April 2 and 8; May 7; June 21; July 7, 22, 23, 26, 28, and 30; August 12 and 25; September 10 and 11; October 12; December 21, 22, and 29, 2004; and January 4, 2005.

This new drug application provides for the use of ABRAXANE™ for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) 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 anthracyline unless clinically contraindicated.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-660**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated January 4, 2004. These commitments are listed below.

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.

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

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 Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study 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 one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Sheila Ryan, Pharm.D., Regulatory Project Manager, at (301) 594-5771.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Grant Williams
1/7/05 12:04:29 PM
Signed for Dr. Pazdur