DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 65-375

Abraxis Pharmaceutical Products
Attention: Toni A. Glinsey
RIVERWAY ONE
6133 N. River Road, Suite 500
Rosemont, IL 60018

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 13, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cefotetan for Injection USP, 10 g/vial (Pharmacy Bulk Package). We note that this product is subject to the exception provisions of section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated April 4, April 24, May 8, May 23, June 15, June 26, and November 22, 2006; and March 7, March 28, April 27, July 18, July 19, and July 30, 2007 (2 submissions).

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Cefotetan for Injection, 10 g/vial (Pharmacy Bulk Package), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Cefotan® for Injection, 10 g/vial (Pharmacy Bulk Package), of AstraZeneca.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs

should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

Gary Buehler
8/9/2007 11:57:34 AM