DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-498/S-016

AstraZeneca Pharmaceuticals LP
Attention: Debra N. Shiozawa, Ph.D.
Associate Director—Oncology, Regulatory Affairs
1800 Concord Pike, PO Box 8355
Wilmington, DE 19803-8355

Dear Dr. Shiozawa:

Please refer to your supplemental new drug application dated April 19, 2004, received April 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CASODEX® (bicalutamide) Tablets.

We acknowledge receipt of your submission dated January 25, 2005, which constituted a complete response to our October 21, 2004 action letter.

This supplemental new drug application provides for the labeling revisions to the Physician Insert as follows:

1. CLINICAL PHARMACOLOGY, Mechanism of Action section, page 2, to include language related to antiandrogen withdrawal phenomenon.
2. CLINICAL PHARMACOLOGY, Drug-Drug Interactions section, page 3, to include language indicating drug interaction potential with CASODEX® is unlikely to be of clinical significance.
3. ADVERSE REACTIONS, Postmarketing Experience section, page 14 to include language related to allergic reactions, hypersensitivity and interstitial lung disease.
4. Change an inactive ingredient's name from methylhydroxypropylcellulose to hypromellose for compliance with the Guidance for Industry entitled "Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate – Labeling Enforcement Policy" dated May 2003.

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 and with the minor editorial revisions listed below and indicated in the enclosed labeling under ADVERSE REACTIONS, Postmarketing Experience subsection.

Place a comma after each of the following text "reactions", "urticaria", "disease", and "fibrosis". The paragraph should read as follows:

Postmarketing Experience:
Uncommon cases of hypersensitivity reactions, including angioneurotic edema and urticaria, and uncommon cases of interstitial lung disease, including interstitial pneumonitis and pulmonary fibrosis, have been reported with CASODEX.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling text for the package insert. These revisions are terms of the approval of this application.

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 20-498/S-016**." Approval of this submission by FDA is not required before the labeling is used.

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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 827-7260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation 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/

Daniel A. Shames

5/11/05 06:25:58 PM