DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-498/S018

AstraZeneca Pharmaceuticals, LP
P.O. Box 8355
Wilmington, DE 1980-8355

Attention: Debra N. Shiozawa, Ph.D.
Associate Director, Oncology Regulatory Affairs

Dear Dr. Shiozawa:

Please refer to your supplemental new drug application(s) (NDA) dated April 7, 2005 received April 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CASODEX® (bicalutamide) 50 mg, tablets.

We acknowledge receipt of your submissions dated July 7 and 28, August 18, September 16, and October 17, 2005. Your October 17, 2005 amendment constituted a complete response to our October 7, 2005 approvable letter.

This supplemental new drug application provides for revisions to the Clinical Pharmacology, Clinical Studies, and Indications and Usage sections of the labeling.

We have completed our review of this supplemental new drug application as amended. This supplemental application is approved, effective on the date of this letter, for use as recommended in the agreed-upon attached labeling text submitted October 17, 2005.

The final printed labeling (FPL) must be identical to the attached labeling (package insert submitted October 17, 2005 and attached.

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/S018**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sharon Thomas, Regulatory Project Manager, at (301) 796-1994.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Robert Justice

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