DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-498/SLR-019/SLR-021

AstraZeneca Pharmaceuticals, LP
Attention: Jane Valas, Ph.D.
1800 Concord Pike, P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Valas:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Casodex (bicalutamide) Tablets:

SLR-019 (PAS) dated October 25, 2007, received October 25, 2007, and
SLR-021 (CBE) dated September 11, 2008, received September 11, 2008.

We acknowledge receipt of your submission to SLR-019 dated November 5, 2008.

SLR-019: "Prior Approval" supplemental new drug application provides for conversion of the package insert to the physician labeling rule format and includes a new patient package insert.

SLR-021: "Changes Being Effected" supplemental new drug application provides for a new subsection entitled "Glucose Intolerance" in the PRECAUTIONS section and the "Information for Patients" subsection of the ADVERSE REACTIONS section, "Post marketing" subsection has been revised to include information on glucose intolerance.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (test for package insert) submitted December 18, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-498/S-019/S-021."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to

the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Alberta Davis-Warren, Regulatory Project Manager, at (301) 796-3908.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Labeling

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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