DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-726/S-050/051/052 **APPROVAL LETTER**

AstraZeneca UK Limited
Attention: E. Jane Valas, Ph.D.
Regulatory Affairs
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 Zoladex® Implant, 3.6 mg

We acknowledge receipt of your submissions dated May 15, 2009, June 8, 2009, June 30, 2009, July 1, 2009, July 9, 2009, July 13, 2009, July 17, 2009, July 30, 2009, and August 13, 2009.

NDA/SLR	Letter date	Received date	Provides for
19-726/SLR-050	January 30, 2008	January 30, 2008	PLR conversion
19-726/SLR-051	September 3, 2008	September 3, 2008	Glucose tolerance
19-726/SLR-052	December 11, 2008	December 17, 2008	Psychotic disorders & pituitary tumors

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

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 the requirements for an approved NDA set forth under 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 L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure (Package insert)

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

/s/

ROBERT L JUSTICE
08/31/2009