DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-726/S-042
NDA 20-578/S-020

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

Dear Dr. Shiozawa:

Please refer to your supplemental new drug application dated December 3, 2003, received December 4, 2003, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOLADEX® (goserelin acetate implant) 3.6 mg Depot.

We completed our review of these supplemental new drug applications they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 30 and May 6, 2004.

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, please call Nenita Crisostomo, R.N., Regulatory Project Manager, at (301) 827-4260.

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 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/

Daniel A. Shames

6/24/04 05:34:08 PM