**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-726/S-034

AstraZeneca Pharmaceuticals LP
Attention: Lisa V. DeLuca, Ph.D.
Director, Regulatory Affairs
P.O Box 8355
Wilmington, DE 19803-8355

Dear Dr. DeLuca:

Please refer to your supplemental new drug application dated March 13, 2001, received March 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoladex® (goserelin acetate implant) 3.6 mg Depot.

We acknowledge receipt of your submissions dated July 9 and August 9, 2001, and January 22, 2002. Your submission of January 22, 2002 constituted a complete response to our October 9, 2001 action letter.

This "Changes Being Effected" supplemental new drug application proposes the following changes to the **ADVERSE REACTIONS-General** and the **ADVERSE REACTIONS-Females** sections of the package insert:

**ADVERSE REACTIONS-General**

> "As with other agents in this class, very rare cases of pituitary apoplexy have been reported following initial administration in patients with a functional pituitary adenoma."

**ADVERSE REACTIONS-Females**

> "As with other LHRH agonists, there have been reports of ovarian cyst formation and, when ZOLADEX 3.6 mg is used in combination with gonadotropins, of ovarian hyperstimulation syndrome (OHSS)."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 22, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
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 Jeanine Best, M.S.N., R.N., Senior Regulatory Associate, at (301) 827-4260.

Sincerely,

*{See appended electronic signature page}*

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

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/s/

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Daniel A. Shames

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