DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-578/S-025
NDA 19-726/S-046

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

Dear Dr. Shiozawa:

Please refer to your supplemental new drug application dated June 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOLADEX® (goserelin acetate implant), 10.8 mg and 3.6 mg Depot.

We acknowledge receipt of your submission dated September 28, 2005. These supplemental new drug applications provide for the revision of the package insert to include the verbiage regarding pituitary apoplexy as indicated in the Prior Approval supplement request letter dated May 11, 2005.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended labeling text and, with the minor editorial revision as indicated below for NDA 19-726/S-046, under HOW SUPPLIED section. As agreed upon during the October 13, 2005, teleconference with Dr. Debra Shiozawa, the word "hypodermic" was inadvertently removed from your proposal upon submission and therefore, the text should be as follows:

> "ZOLADEX is supplied as a sterile and totally biodegradable D,L-lactic and glycolic acids copolymer (13.3-14.3 mg/dose) impregnated with goserelin acetate equivalent to 3.6 mg of goserelin in a disposable syringe device fitted with a 16-gauge x 36 +/- 0.5 mm hypodermic siliconized needle with protective needle sleeve [SafeSystem™ Syringe] (NDC 0310-0950-36)."

The final printed labeling (FPL) must be identical, and include the minor revision as indicated above, to the labeling text for the package insert as submitted on September 28, 2005.

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 20-578/S-025 and NDA 19-726/S-046**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Drug Oncology Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, HFD-410
FDA
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

This communication will also serve to inform you that the above-referenced NDAs have been transferred and therefore, all future communications regarding these NDAs shall be directed to the Division of Drug Oncology Products.

If you have any questions regarding this communication, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
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/

Daniel A. Shames

10/19/2005 05:48:42 PM