NDA 19-726/S-024
NDA 20-578/S-003

JUL 27 1998

Zeneca Pharmaceuticals, Inc.
Attention: Ms. Kimi Denoble
Assistant Manager, Marketed Products Group
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437

Dear Ms. DeNoble:

Please refer to your supplemental new drug applications dated August 11, 1997, received August 12, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoladex (goserelin acetate) 3.6 mg Depot, and 10.8 mg Depot.

We acknowledge receipt of your submissions dated August 28, 1997, and April 9, June 12, July 21, and 24 1998. The user fee goal date for these applications is August 12, 1998.

These supplemental new drug applications provide for the use of Zoladex (goserelin acetate) 3.6 mg and 10.8 mg Depots in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling for the package insert dated July 21, 1998, for the 3.6 mg Depot, and identical to the submitted draft labeling for the package insert dated July 24, 1998, for the 10.8 mg Depot. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplemental NDAs 19-726/S-024 and 20-578/S-003.@ Approval of these submissions by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

If a letter communicating important information about this drug product (i.e., a ADear Healthcare Practitioner@ 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

Please submit one market package of the drug product when it is available.

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, contact Alvis Dunson, Project Manager, at (301) 827- 4260.

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research