CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19726/S18

APPROVAL LETTER

NDA 19-726/S-018

JUN 27 1997

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

Dear Ms. DeNoble:

Please refer to your supplemental new drug application dated June 28, 1996, received June 28, 1996, 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 3, August 12, 13 and 23, 1996; January 31, February 26 (2), March 7 and 14, May 12, and June 10, 16, 19, 26, and 27, 1997. The User Fee goal date for this application is June 28, 1997.

The supplemental application provides for the use of Zoladex as an endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

We have completed the review of this supplemental application, including the submitted draft labeling, 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 draft labeling in the submission dated June 10, 1997 (cartons and pouches) and June 27, 1997 (physician package insert). Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 27, 1997.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 19-726/S-018. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. 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 material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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, please contact Alvis Dunson, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

Heidi Dolan for LR 6/27/97
Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Drafted by: ADunson/June 11, 1997/n19726.18ap

Concurrences:

NAME	TITLE	SIGNATURE	DATE
Lana L. Pauls, M.P.H.	Chief, Project Management Staff for		6/27/97
Heidi Jolson, M.D., M.P.H.	Deputy Division Director		6/27/97
Moo-Jhong Rhee, Ph.D.	Chemistry Team Leader		6/27/97
Krishan Raheja, D.V.M., Ph.D.	Pharmacologist		6/27/97
Alex Jordan, Ph.D.	Pharmacology Team Leader		6/27/97
K. Gary Barnette, Ph.D.	Pharmacokineticist		6/27/97
Angelica Dorantes, Ph.D.	Pharmacokinetics Team Leader		6/27/97
Kate Meaker, M.S.	Statistician		6/27/97
Lisa Kammerman, Ph.D.	Statistical Team Leader		6/27/97
Lisa Rarick, M.D.	Division Director		6/27/97

cc:
Original NDA 19-726
HFD-580/Div. files
HFD-580/CSO/ADunson
HFD-580/HJolson/MRhee/KRaheja/AJordan/GBarnette/ADorantes
HFD-580/KMeaker/LKammerman/LRarick
HFD-002/ORM (with labeling)
HFD-102/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFD-560/OTC (with labeling - for OTC Drug Products Only)
HFI-20/Press Office (with labeling)

APPROVAL (AP)