CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-708

APPROVAL LETTER

Dunson

NDA 20-708

MAR 7 1997

TAP Holdings, Inc.
Attention: Aruna Dabholkar, M.D.
Associate Director, Regulatory Affairs
2355 Waukegan Road
Deerfield, IL 60015

Dear Dr. Dabholkar:

Please refer to your new drug application dated March 6, 1996, received March 8, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot® (leuprolide acetate), 3-Month, 11.25 mg.

We acknowledge receipt of your submissions dated May 1, 1996, January 3 and 22, February 7, 24 and 27, and March 6 and 7 (telefascmile), 1997.

The User Fee goal date for this application is March 7, 1997.

This new drug application provides for a 3-Month Depot formulation for:

1) the management of endometriosis, including pain relief and reduction of endometriotic lesions; and

2) preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids) when used concomitantly with iron therapy.

We have completed the review of this 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 submissions dated March 6, 1996 (cartons and pouches) and March 7, 1997 (patient package insert and physician package insert). Accordingly, the application is approved, effective on the date of this letter.

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 NDA 20-708. 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.

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,

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

ENCLOSURE

cc:
Original NDA 20-708
HFD-580/Div. files
HFD-580/CSO/ADunson
HFD-580/PCorfman/LRarick/HJolson/MRhee
HFD-580/GBarnette/ADorantes/Kraheja/AJordan/LPauls
HFD-002/ORM (with labeling)
HFD-102/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
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)
HFI-20/Press Office (with labeling)

Drafted by: ADunson/February 25, 1997/n20708ap

Concurrences:

NAME	TITLE	SIGNATURE	DATE
Lana Pauls, M.P.H.	Chief, Project Management Staff		3/27/97
Philip Corfman, M.D.	Medical Officer		02 27.97.
Heidi Jolson, M.D, M.P.H.	Deputy Division Director		3/3/97
Moo-Jhong Rhee, Ph.D.	Chemistry Team Leader		3/3/97
Krishan Raheja, D.V.M., Ph.D.	Pharmacologist	Krishan L Raheja	3/3/97
Alex Jordan, Ph.D.	Pharmacology Team Leader		3/3/97
K.Gary Barnette, Ph.D.	Pharmacokineticist		3/3/97
Angelica Dorantes, Ph.D.	Pharmacokinetics Team Leader		3/3/97
Lisa Rarick, M.D.	Division Director		3/4/97

APPROVAL (AP)