CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19732/S012

APPROVAL LETTER

NDA 19-732/S-012

JAN 9 1998

TAP Holdings Inc.
Attention: Aruna Dabholkar, M.D.
Regulatory Products Manager
2355 Waukegan Road
Deerfield, IL 60015

Dear Dr. Dabholkar:

Please refer to your supplemental new drug application dated February 19, 1996, received February 20, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and the provisions of 21 CFR 314.70(c) for Lupron Depot 7.5 mg (leuprolide acetate for depot suspension).

The supplemental application provides for the addition of information to the "**Postmarketing**" subsection of the **ADVERSE REACTIONS** section of the Physician Insert. Specifically, this subsection begins with three new paragraphs that read:

> "During postmarketing surveillance, which includes other dosage forms, the following adverse events were reported.
>
> Symptoms consistent with an anaphylactoid or asthmatic process have been rarely reported with GnRH analogs. Rash, urticaria, and photosensitivity reaction have also been reported.
>
> Localized reactions including induration and abscess have been reported at the site of injection."

Additionally, the diluent ampules are changed from 1.5 mL to 2 mL throughout the labeling to allow for common labeling of all Lupron Depot products.

We have completed the review of this supplemental application, including the submitted final printed 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 final printed labeling in the submission dated April 15, 1996. Accordingly, the supplemental application is approved.

We also refer to your amendment dated April 15, 1996, containing final printed labeling for this supplemental application.

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

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

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 Christina Kish, Project Manager, at (301) 827-4260.

Sincerely,

/S/ 1/9/98

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

cc:
Orig. NDA
HFD-580
HFD-580/DShames/HJolson
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)
HFD-580/CKish/12.9.97/n19732ap.s12
concurrence:LPauls 12.16.97/DShames 12.16.97/HJolson 1.7.98

SUPPLEMENT APPROVAL (S/AP)