CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20011/S14

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-011/S-014
NDA 20-708/S-003

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

APR 09 1998

Dear Dr. Dabholkar:

Please refer to your supplemental new drug applications dated September 22, 1997, received September 23, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot® (leuprolide acetate for depot suspension) 3.75 mg and 11.25 mg.

We acknowledge receipt of your submissions dated January 22, February 16, and April 9, 1998. The User Fee goal date for these applications is September 23, 1998.

These supplemental applications provide for an addition to the CLINICAL STUDIES, PRECAUTIONS, and ADVERSE REACTIONS sections regarding the use of hormone replacement therapy in reducing the bone mineral density loss associated with the use of Lupron Depot alone for the treatment of endometrosis.

We have completed the review of these supplemental applications, including the submitted draft labeling, 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 draft labeling in the submissions dated April 9, 1998. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on April 9, 1998.

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 NDAs 20-011/S-014, 20-708/S-003. 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 drugs 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 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 material and the package inserts 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 these drug products (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 these NDAs 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, Project Manager, at (301) 827-4260.

Sincerely,

/S/

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