DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-943/S-018
20-011/S-025
20-708-S-015

TAP Pharmaceutical Products Inc.
Attention: Jessie Y. Lee, Ph.D., RAC
Senior Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lee:

Please refer to your supplemental new drug applications dated August 21, 2003, received August 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot® 3.74 mg, Lupron Depot® 3.75 mg, 22.5 mg and Lupron Depot® 3 Month 11.25 mg (leuprolide acetate for depot suspension).

These supplemental new drug applications provide for the recommended changes in the July 24, 2003 approvable letter.

We have completed the review of these supplemental applications 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 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 labeling dated August 21, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 "FPL for approved supplement NDA 19-943/S-018, NDA 20-011/S-025 and NDA 20-708/S-015." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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