DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-263/S-028

TAP Pharmaceutical Products, Inc.
Attention: Tanya Haynes
Regulatory Affairs Product Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Haynes:

Please refer to your supplemental new drug application dated August 18, 2005, received August 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron (leuprolide acetate) Injection, 5 mg/ml (for pediatric use) and Lupron Depot-Ped (leuprolide acetate for depot suspension), 7.5, 11.25, and 15 mg prefilled syringes.

This supplemental new drug application provides for revision to the package inserts to add pituitary apoplexy to the **Postmarketing** subsection of the **ADVERSE REACTIONS** section.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package inserts).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-263/S-028**." Approval of this submission 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Division Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center of Drug Evaluation and Research

Enclosures: draft package inserts:

1. Lupron Injection, 5 mg/mL (for pediatric use)
2. Lupron Depot-Ped, 7.5 mg, 11.25 mg and 15 mg, prefilled, dual-chamber syringes

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

/s/

Mary Parks

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