**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-010/S-027

TAP Pharmaceutical Products, Inc.
Attention: John R. Lieberman, Ph.D.
Principal Regulatory Adviser
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lieberman:

Please refer to your supplemental new drug application dated May 30, 2003, received June 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron® (leuprolide acetate) Injection.

We also acknowledge receipt of your submissions dated July 14 and September 19, 2003.

This supplemental new drug application provides for proposed language for Geriatric Use subsection.

We have completed the review of this supplemental application 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, this supplemental application is approved effective on the date of this letter.

However, we recommend that in the geriatric use statement, use the word “were” instead of “was” in reference to the majority of subjects. The final printed labeling (FPL) must otherwise be identical to the submitted labeling dated May 30, 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 19-010/S-027.” 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, 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

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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.**

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/s/

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Daniel A. Shames

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