DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-010/S-032

TAP Pharmaceutical Products Inc.
Attention: Allison Villinski
Regulatory Project Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Villinski:

Please refer to your supplemental new drug application dated December 18, 2006, received December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Injection (leuprolide acetate).

This "Changes Being Effected" supplemental new drug application provides for changes to the Adverse Reactions section of the label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 18, 2006.

We also refer to your October 28, 2005 submission which provided FPL for approved supplement 19010/S-031. The October 28, 2005 submission has been superseded and is acknowledged and retained.

If you have any questions, call Paul Zimmerman, Regulatory Project Manager, at 301-796-1489.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Robert Justice

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