



NDA 20-263/S-026

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 May 6, 2005, received May 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron PED (leuprolide acetate/injection/depot suspension).

This "Changes Being Effected" supplemental new drug application provides for addition of an appearance test to ensure the microsphere powder is free-flowing in the pre-filled syringes. It also adds statements (in the package insert and How to Mix and Administer booklet) to instruct health care professionals and patients/guardians to visually inspect the powder for caking or clumping prior to mixing and administration.

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 6, 2005.

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
How to Mix and Administer booklet

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff
11/9/2005 03:51:59 PM