



NDA 20-263/S-022

TAP Pharmaceuticals, Inc.
Attention: Jessie Y. Lee, Ph.D.
Principal Regulatory Advisor
675 North Field Drive
Lake Forrest, Illinois 60045

Dear Dr. Lee:

Please refer to your supplemental new drug application dated April 25, 2003, received April 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot PED (leuprolide acetate/depot suspension/injection).

This "Changes Being Effected" supplemental new drug application provides for the addition of a Geriatric Use subsection in the PRECAUTIONS section of the package insert. Also, this supplement provides for clarification of the administration statements in the DOSAGE AND ADMINISTRATION section of the package insert and the Instructions on How to Mix and Administer.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling submitted on April 25, 2003, (see the revision below) per the discussion on October 27, 2003, between you and Monika Johnson of this division. This revision can be reported to the Agency in the next annual report for this application.

Geriatric Use See also the labeling for the LUPRON DEPOT 7.5 mg which is indicated for the palliative treatment of advanced prostate cancer. For LUPRON DEPOT-PED 11.25 mg and LUPRON DEPOT-PED 15 mg, no clinical information has been established for persons aged 65 and over.

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 Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products,
HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

David Orloff
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