



NDA 19-010/S-028

TAP Pharmaceutical Products, Inc.
Attention: Jessie Y. Lee, Ph.D., R.A.C.
Senior Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lee:

Please refer to your supplemental new drug application dated August 28, 2003, received September 2, 2003, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LUPRON[®] (leuprolide acetate) Injection. This supplemental new drug application provides for the revision of the package insert.

We acknowledge receipt of your submissions dated July 2, 15, 27, and August 9, 2004. Your submission of August 9, 2004, constituted a complete response to our June 24, 2004, action letter.

We completed our review of this application, as amended. This application 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 package insert submitted August 9, 2004.

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 15 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-028." Approval of this submission by FDA is not required before the labeling is used.

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}

Donna Griebel, M.D.
Deputy Director
Division Of Reproductive and Urologic Drug products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

Donna Griebel
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