



NDA 19-943/S-026
NDA 20-011/S-033
NDA 20-708/S-026

TAP Pharmaceutical Products, Inc.
Attention: Leslie D. Abelson, R.A.C.
Assistant Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Abelson:

Please refer to your supplemental new drug applications dated April 27, 2007, received April 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot[®] (leuprolide acetate for depot suspension), 3.75 mg, and Lupron Depot[®] (leuprolide acetate for depot suspension), 3 Month, 11.25 mg.

We acknowledge receipt of your submission dated October 26, 2007.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the phrase "FOR ADULT USE" on the product packaging label and mixing instructions.

We have completed our review of these applications, as amended. These applications are 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 submitted labeling (product packaging label and mixing instructions submitted on October 26, 2007).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-943/S-026, NDA 20-011/S-033, and NDA 20-708/S-026.**" Approval of these submissions by FDA is not required before the labeling is used.

NDA 19-943/S-026
NDA 20-011/S-033
NDA 20-708/S-026
Page 2

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic
Products
Office of Drug Evaluation III
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/

Scott Monroe
10/31/2007 11:11:05 AM