DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-732/S-027, S-029 20-517/S-018, S-019
19-010/S-031 20-708/S-020, S-021
19-943/S-022, S-024 20-011/S-029, S-031

TAP Pharmaceutical Products Inc.
Attention: Tonya Haynes, M.P.H.
Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Haynes:

Please refer to your supplemental new drug applications as listed below, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

NDA	Supplement	Name of Drug	Letter Date	Receipt Date
19-732	SCS-027	Lupron Depot (leuprolide acetate for depot suspension), 7.5mg	May 6, 2005	May 9, 2005
19-732	SLR-029	Lupron Depot (leuprolide acetate for depot suspension), 7.5mg	August 18, 2005	August 19, 2005
20-517	SCS-018	Lupron Depot (leuprolide acetate for depot suspension), 4-month, 30mg	May 6, 2005	May 9, 2005
20-517	SLR-019	Lupron Depot (leuprolide acetate for depot suspension), 4-month, 30mg	August 18, 2005	August 19, 2005
19-010	SLR-031	Lupron Injection (leuprolide acetate	August 18, 2005	August 19, 2005
20-708	SCS-020	Lupron Depot (leuprolide acetate for depot suspension), 3-month	May 6, 2005	May 9, 2005
20-708	SLR-021	Lupron Depot (leuprolide acetate for depot suspension), 3-month	August 18, 2005	August 19, 2005
19-943	SCS-022	Lupron Depot (leuprolide acetate for depot suspension), 3.75 mg	May 6, 2005	May 9, 2005
19-943	SLR-024	Lupron Depot (leuprolide acetate for depot suspension), 3.75 mg	August 18, 2005	August 19, 2005
20-011	SCS-029	Lupron Depot (leuprolide acetate for depot suspension), 3.75mg	May 6, 2005	May 9, 2005
20-011	SLR-031	Lupron Depot (leuprolide acetate for depot suspension), 3.75mg	August 18, 2005	August 19, 2005

The Prior Approval supplemental new drug applications dated August 18, 2005, provide for changes in the package insert to include text regarding pituitary apoplexy.

The "Changes Being Effected" supplemental new drug applications dated May 6, 2005, provide for the addition of an appearance test, and changes in the package insert and mixing instructions regarding the LUPRON recall.

We completed our review of these applications, they 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 (package insert, mixing instructions) on August 18, 2005.

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 ##-###/S-YYY, S-ZZZ**", specific to the applications as listed above. Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of DIVISION NAME and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, HFD-410
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

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) 827-7260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
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 this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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