



NDA 21-288/S-002
NDA 20-715/S-006

Watson Laboratories, Inc.
Attention: Kevin Barber, Ph.D., R.A.C., P.M.P.
Director, Regulatory Affairs—Proprietary Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Barber:

Please refer to your supplemental new drug applications dated August 4, 2005, received August 5, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TRELSTAR[®] (triptorelin pamoate) Depot and LA.

We acknowledge receipt of your submission dated and September 16, 2005.

This supplemental new drug application provides for a change in the labeling to include text regarding pituitary apoplexy.

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 as amended on September 16, 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 this submission "**FPL for approved supplement NDA 21-288/S-002, NDA 20-715/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

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

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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) 796-2130.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic
Products
Office of Drug Evaluation III
Center of Drug Evaluation and Research

Enclosure

**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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