DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-715/S-016
NDA 21-288/S-013

Watson Laboratories, Inc.
Attention: Burke Byrne
Associate, Regulatory Affairs, CMC
577 Chipeta Way
Salt Lake City, Utah 84108

Dear Mr. Byrne:

Please refer to your supplemental new drug applications dated September 17, 2007, received September 18, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	Supplement	Drug Product
NDA 20-715	S-016	Trelstar® Depot (triptorelin pamoate for injectable suspension) 3.75 mg
NDA 21-288	S-013	Trelstar® LA (triptorelin pamoate for injectable suspension) 11.25 mg

We acknowledge receipt of your submissions dated November 12, 2007, and January 24, 2008. Your submission of January 24, 2008, constituted a complete response to our January 18, 2008, action letter.

These "Prior Approval" supplemental new drug applications provide for an alternate reconstitution system; the MIXJECT®, a new secondary terminal sterilization method, and applicable revised labeling.

We 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 text for the package insert submitted November 12, 2007, and the immediate container and carton labels submitted January 24, 2008.

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 supplements NDA 20-715/S-016; NDA 21-288/S-013**." Approval of these submissions by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated March 13, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Promotional materials should be submitted, in duplicate, directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
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
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, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure: None

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel
4/14/2008 01:29:13 PM