



NDA 020715/S-030, NDA 021288/S-027, and NDA 022437/S-007

SUPPLEMENT APPROVAL

Watson Laboratories, Inc.
Attention: Wendy DeSpain, B.S., M.B.A., RAC
Director, Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Ms. DeSpain:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 11, 2013, received February 12, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Product Name
NDA 020715	S-030	Trelstar® (triptorelin pamoate for injectable suspension), 3.75 mg
NDA 021288	S-027	Trelstar® (triptorelin pamoate for injectable suspension), 11.25 mg
NDA 022437	S-007	Trelstar® (triptorelin pamoate for injectable suspension), 22.5 mg

These “Prior Approval” supplemental new drug applications propose adding “convulsions” to the Section 6.2 Postmarketing Experience of Section 6 ADVERSE REACTIONS as requested in FDA’s Supplement Request letter dated January 15, 2013.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement numbers and annual report dates.

REPORTING REQUIREMENTS

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 Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Katherine Fedenko, M.S., C.R.N.P.
Deputy Director for Safety
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center of Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

GENEVIEVE A SCHECHTER
03/12/2013