CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-437

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

June 17, 2009

NDA: 22-437

Drug Product Name
Proprietary: Trelstar 22.5 mg
Non-proprietary: triptorelin pamoate injectable suspension.

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
September 12, 2008	September 12, 2008	November 12, 2008	November 13, 2008

Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: Watson Laboratories, Inc.
Address: 577 Chipeta Way, Salt Lake City, UT 84108
Representative: Wendy DeSpain, Assoc. Director, Reg. Affairs
Telephone: 801-588-6268

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: An approved product formulation presentation for a 6 month sustained release.

3. MANUFACTURING SITE: Debio Recherche Pharmaceutique SA
Route du Levant 146, CH-1920 Martigny
Switzerland

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
Triptorelin pamoate 22.5 mg is a sterile, lyophilized microgranule formulation supplied as a single-dose vial for sustained release of 3.75 mg per month over 6 months. The suspension is intended for intramuscular injection to be administered every 168 days (i.e., every 24 weeks). Product comes in one of two packaging configurations (1) A single drug product vial (2) A single drug product vial packaged with the MIXJECT reconstitution system.

5. METHOD(S) OF STERILIZATION: [redacted] (b) (4) of both the lyophilized powder in vials and the MIXJECT reconstitution system.

6. PHARMACOLOGICAL CATEGORY: Prostrate cancer treatment.

B. SUPPORTING/RELATED DOCUMENTS: DMF 8084 for Pre-filled WFI Syringes.

C. REMARKS:
For the subject NDA 22-437, the sponsor proposes to manufacture 22.5mg Trelstar Depot (sustained release of 3.75mg per month over 6 months) using the same process approved for Trelstar Depot 3.75mg (1-month sustained release, NDA 20-715) and Trelstar Depot 11.25mg (3-month sustained release, NDA 21-288). The new presentation will use the same container closure system and will be terminally sterilized by the same [redacted] (b) (4) process used for sterilization of the approved Trelstar LA formulations. The approved terminal sterilization process was validated based on complete inactivation of biological indicators (BIs) at both [redacted] (b) (4) cycles. For updated information on the validation of the [redacted] (b) (4) sterilization method, refer to Supplements S-004 to NDA 20-715 and S-008 to NDA 21-288, submitted on 12 January 2006 and approved on 08 May 2006.

filename: **C:\my documents\review\NDA\N022437R1**

Executive Summary

I. Recommendations

A. Recommendation on Approvability - The application is recommended for approval.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – There are no changes in the manufacturing process except for the new excipient [redacted] (b) (4) to provide a [redacted] (b) (4) for sustained release of the product.

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____
David Hussong, Ph.D.

C. CC Block
N/A

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

/s/

Vinayak Pawar
6/19/2009 11:25:06 AM
MICROBIOLOGIST
The application is recommended for approval.

David Hussong
6/22/2009 05:17:26 PM
MICROBIOLOGIST
I concurr with the reviewer's recommendation to approve this supplement.