CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-088

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

2-MARCH-2007

NDA: 22-088
22-088-BZ
22-088-BC

Drug Product Name
Proprietary: TORISEL™
Non-proprietary: Temsirolimus Injection
Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
10/5/06	10/5/06	10/13/06	10/24/06
1/19/07	1/19/07	N/A	N/A
2/23/07	2/23/07	N/A	N/A

Submission History (for amendments only): Not applicable

Applicant/Sponsor
Name: Wyeth Pharmaceuticals Inc.
Address: 35 Cambridge Park Dr.
Cambridge, MA 02140

Representative: Patricia M. Johnson
Telephone: (617) 665-8623

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: Sterilization validation of drug product and diluent.

3. MANUFACTURING SITE:
The drug product will be manufactured at:

Pierre Fabre Medicament Production Aquitaine Pharm International 1 Avenue du Bearn – F 64320
Idron, France
FEI: 3004136115

The diluent will be manufactured at:

Ben Venue Laboratories, Inc.
300 Northfield Road
P.O. Box 46568
Bedford, Ohio 44146-0568
USA
FEI 1519257

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Concentrate for injection
- 25 mg/vial
- intravenous

5. METHOD(S) OF STERILIZATION: [redacted]

6. PHARMACOLOGICAL CATEGORY: cancer therapy

B. SUPPORTING/RELATED DOCUMENTS: DMFs 9642, 2315, [redacted]

C. REMARKS: This application was submitted as part of the CDER quality by design pilot program. It is an electronic submission provided in CTD format. The Initial Quality Assessment (IQA) was provided by Dr. Sarah Pope and entered into DFS on November 27, 2006. The IQA calls for a microbiology consult to be initiated.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 22-088 is recommended for approval on the basis of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -
Temsirolimus injection and diluent for temsirolimus injection will be [redacted] processed at separate manufacturing facilities.

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -
Not applicable

III. Administrative

A. Reviewer's Signature _____
Stephen E. Langille, Ph.D.

B. Endorsement Block _____
Bryan Riley, Ph.D.

C. CC Block
N/A

15 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology-1

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

/s/

Stephen Langille
3/2/2007 09:33:32 AM
MICROBIOLOGIST

Bryan Riley
3/2/2007 09:40:14 AM
MICROBIOLOGIST