CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-080

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

05 February 2007

NDA: 22-080

Drug Product Name
Proprietary: Reclast®
Non-proprietary: zoledronic acid.
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
16 October 2006	17 October 2006	06 November 2006	09 November 2006

Applicant/Sponsor
Name: Novartis Pharmaceuticals Corp.
Address: One Health Plaza
East Hanover, NJ 07936-1080
Representative: Lynn Mellor
Telephone: 862-778-3665

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommended for approval.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original New Drug Application.

2. **SUBMISSION PROVIDES FOR:** A new drug product.

3. **MANUFACTURING SITE:**
Novartis Pharma Stein AG
Schaffhauserstrasse
4332-Stein
Switzerland

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- 100 mL solution in _____ vials.
- Intravenous Infusion.
- 5 mg/100 mL.

5. **METHOD(S) OF STERILIZATION:** _____

6. **PHARMACOLOGICAL CATEGORY:** Indicated for the treatment of post menopausal osteoporosis.

B. **SUPPORTING/RELATED DOCUMENTS:** Microbiology review (dated 08 February 2005) of NDA 21-817.

C. **REMARKS:**
The submission was provided electronically in the CTD format.

The subject submission cross-references NDA 21-817 regarding the drug product and its manufacture and control. NDA 21-817 was recommended for approval with regard to product quality microbiology issues in a review dated 08 February 2005.

An Initial Quality Assessment was performed by the ONDQA PAL and states the following regarding the microbiology consult:

"Consult request will be sent by the PM for the evaluation of microbial limits and preservative effectiveness test/results."

Reviewer's Comment

Neither evaluation of microbial limits nor preservative effectiveness is relevant to the microbiological quality of the subject drug product since the drug product is manufactured both sterile and lacking a preservative.

File Name: N022080R1.doc

Executive Summary

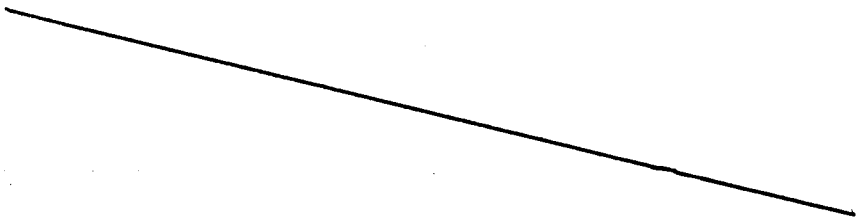
I. Recommendations

A. Recommendation on Approvability – NDA 22-080 is recommended for approval with regard to product quality microbiology.

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 –



B. Brief Description of Microbiology Deficiencies – There are no microbiology deficiencies identified.

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

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Stephen Langille, Ph.D.

C. CC Block
N/A

3 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/

John Metcalfe
2/16/2007 01:31:00 PM
MICROBIOLOGIST

Stephen Langille
2/16/2007 01:44:27 PM
MICROBIOLOGIST