CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-484

Microbiology Review(s)

Product Quality Microbiology Review
Consult Review for HFD-580

25 April 2002

NDA: 21-484

Name of Drug: Bravelle™

Review Number: 1

Submission Date: 15 February 2002

Applicant: Ferring Pharmaceuticals

Name of Reviewer: Paul Stinavage

Product Quality Microbiology Data Sheet

A. 1. **NDA:** 21-484

2. **REVIEW NUMBER:** 1

3. **REVIEW DATE:** 25 April 2002

4. **TYPE OF SUPPLEMENT:** N/A

5. **SUPPLEMENT PROVIDES FOR:** N/A

6. **APPLICANT/SPONSOR:** Ferring Pharmaceuticals, Inc.
120 White Plains Road, Suite 400
Tarrytown, NY 10591

Name: Ferring Pharmaceuticals
Representative: Ronald Nardi
Telephone: (914)333-8932

7. **MANUFACTURING SITE:** Albuquerque, NM

8. **DRUG PRODUCT NAME:**
Proprietary: Bravelle™
Non-proprietary: purified urofollitropin
Drug Priority Classification: Standard

9. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Injectable

10. **METHOD(S) OF STERILIZATION:** —

11. **PHARMACOLOGICAL CATEGORY:** Lyophilized powder for reconstitution

B. 1. **DOCUMENT/LETTER DATE:** 15 February 2002
2. **RECEIPT DATE:** 19 February 2002
3. **CONSULT DATE:** 22 February 2002
4. **DATE OF AMENDMENTS:** (none)
5. **ASSIGNED FOR REVIEW:** 27 February 2002
6. **SUPPORTING/RELATED DOCUMENTS:** (none)

C. **REMARKS:** The submission is an administrative New Drug Application for the Assisted Reproductive Technologies clinical indication for the drug product. This administrative NDA is referenced to NDA 21-289. NDA 21-289 was recommended for approval on the basis of sterility assurance in Microbiologist's Review #3 dated 23 May 2001.

Executive Summary

I. Recommendations

Recommendation on Approvability – The referenced NDA, NDA 21-289 was recommended for approval in Microbiologist's Review #3 dated 23 May 2001. Therefore, since the current submission makes no changes to the drug product manufacturing process, the submission is recommended for approval on the basis of sterility assurance.

B. Recommendation 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

The product is an sterile lyophilized preparation for reconstitution and injection.

B. Brief Description of Microbiology Deficiencies

C. Assessment of Risk Due to Microbiology Deficiencies-

III. Administrative

A. Reviewer's Signature _____ S

B. Endorsement Block

Paul Stinavage/25 April 2002
P.H. Cooney/
A. Reddy/

C. CC Block

cc:
Original NDA 21-484
HFD-580/Division File/NDA 21-484

Product Quality Microbiology Assessment

The submission is an administrative NDA. All product manufacturing and sterilization information ~~is r~~eferenced to NDA 21-289. NDA 21-289 was recommended for approval in Microbiologist's Review #3 dated 23 May 2001.

Satisfactory

APPEARS THIS WAY
ON ORIGINAL

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

/s/

Paul Stinavage
5/17/02 05:44:03 AM
MICROBIOLOGIST
Administrative NDA all information referenced to NDA 21-289. NDA 21-289 recommended for approval 23 May 2001..

Peter Cooney
5/17/02 08:29:45 AM
MICROBIOLOGIST