CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-584

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD-580

26 MARCH 2004

NDA: 21-584

Drug Product Name
Proprietary:
Non-proprietary: Medroxypregesterone Acetate Subcutaneous Injection
Drug Product Priority Classification: P

Review Number: 1

Subject of this Review
Submission Date: 17 December 2003
Receipt Date:
Consult Date: 29 December 2003
Date Assigned for Review: 12 January 2004

Submission History (for amendments only)
Date(s) of Previous Submission(s): N/A
Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor
Name: Pfizer, Inc
Address: 2800 Plymouth Road; Ann Arbor, MI 48105
Representative: Daniel Chirby
Telephone: 734-622-3750

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** N/A

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

3. **MANUFACTURING SITE:** Pharmacia NV/SA
Rojksweg 12
B-2870 Puurs – Belgium

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile Injectable Suspension in a pre-filled syringe, subcutaneous injection, 104 mg/0.65 mL

5. **METHOD(S) OF STERILIZATION:** –

6. **PHARMACOLOGICAL CATEGORY:** Endometriosis

B. **SUPPORTING/RELATED DOCUMENTS:** Product Quality Microbiology review of NDA 21-583 (review dated 10 February 2004)

C. **REMARKS:** The drug product in this application is identical to the drug product in NDA 21-583. NDA 21-583 was recommended for approval in product quality microbiology review dated 10 February 2004.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of 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 - The drug product is

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies - The drug product is manufactured using a
Therefore, the drug product presents a minimal risk from the standpoint of product quality microbiology.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)

C. CC Block
N/A

1 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Bryan Riley
4/2/04 10:26:50 AM
MICROBIOLOGIST

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