

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-583

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-580

10 FEBRUARY 2004

NDA: 21-583

Drug Product Name

Proprietary: N/A

Non-proprietary: Medroxyprogesterone acetate injectable suspension

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 30 June 2003

Receipt Date: 2 July 2003

Consult Date: 22 September 2003

Date Assigned for Review: 24 October 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s):

Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Pharmacia and Upjohn

Address: 7000 Portage Rd.; Kalamazoo, MI 49001

Representative: Daniel G. Chirby

Telephone: 269-833-9411

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:
 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: Birth control
- B. SUPPORTING/RELATED DOCUMENTS: DMF —
- C. REMARKS: —
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/s/

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