CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
76-553

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-620

June 20, 2003

ANDA: 76-553

Drug Product Name
Proprietary: N/A
Non-proprietary: Medroxyprogestrone Acetate Injectable Suspension, USP
Drug Product Classification: Contraceptive

Review Number: #1

Subject of this Review
Submission Date: November 27, 2002
Receipt Date: November 29, 2002
Consult Date: N/A
Date Assigned for Review: June 16, 2003

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: Gensia Sicor Pharmaceuticals, Inc.
Address: 19 Hughes, Irvine, CA 92618-1902
Representative: Elvia O. Gustavson
Telephone: 949-455-4724

Name of Reviewer: Nrapendra Nath

Conclusion: The submission is **recommended** for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

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

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

3. **MANUFACTURING SITE:**
Gensia Sicor Pharmaceuticals
19 Huges
Irvine, CA 92618

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 150mg/mL as 1mL fill in 2mL Vial; I/M

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

6. **PHARMACOLOGICAL CATEGORY:** Contraceptive

B. **SUPPORTING/RELATED DOCUMENTS:** ANDA 76-552

C. **REMARKS:** The subject ANDA is similar to ANDA 40-454, which was reviewed by the subject reviewer in June 2002, in its sterility assurance content.

The ANDA 76-552 is similar to the subject ANDA except that it is filled in glass syringes instead of glass vials.

APPEARS THIS WAY
ON ORIGINAL

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in the "Product Quality Microbiology Assessment" section.

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 subject drug product consists of a suspension and is manufactured [redacted] as single dose in glass vials.

B. Brief Description of Microbiology Deficiencies -

None.

C. Assessment of Risk Due to Microbiology Deficiencies -

None.

III. Administrative

A. Reviewer's Signature

Nrapendra Nath 7/9/03

B. Endorsement Block

Microbiologist / Nrapendra Nath
Microbiology Team Leader/Neal J. Sweeney

Neal J Sweeney 7-10-03

C. CC Block

cc:
Original ANDA
HFD- 600
Division File
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MICROBIOLOGY REVIEW #1