APPLICATION NUMBER:
21-529

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review
Review for HFD-580

7 May 2004

NDA: 21-529/N-000 BC

Drug Product Name
- Proprietary: Implanon™ 68 mg
- Non-proprietary: etonorgestrel subdermal implant
Drug Product Classification: Contraceptive

Review Number: 1

Subject of this Review
- Submission Date: 30 September 2003 (See Remarks)
- Receipt Date: 1 October 2003
- Consult Date: 2 April 2004
- Date Assigned for Review: 31 March 2004 (See Submission History)

Submission History (for amendments only)
- Date(s) of Previous Submission(s): 18 March 2004
- Date(s) of Previous Micro Review(s): 22 January 2004

Applicant/Sponsor
- Name: Organon
- Address: 375 Mt. Pleasant Avenue, West Orange, NJ 07052
- Representative: Edwina Muir
- Telephone: (973) 325-4540

Name of Reviewer: Paul Stinavage, Ph.D.

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: N.V. Organon, Molenstraat 110, 5342 CC Oss, The Netherlands
    4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 68 mg of etonogestrel
    5. STERILIZATION METHOD(S): b(4)
    6. PHARMACOLOGICAL CATEGORY: contraceptive

B. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS: This review covers two consult requests from Dr. Amit Mitra, the review chemist. One document is labeled as an original amendment (N000BC) and the second is the drug substance specifications copied from the original NDA. The chemist has requested: (1.) Review of the microbial limits specification for the drug substance and (2.) Deletion of the test used for product packaging.

The test performed on packaged product will be deleted. In addition, defects on the blister packaging and improper defects have been re-classified from “Major” to “Critical” defects.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – The submission is recommended for approval on the basis of sterility assurance.

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 packaged product is b(4)

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer’s Signature

B. Endorsement Block
   P. Stinavage
   P. Cooney

C. CC Block
   cc:
   Original NDA 21-529
   HFD-580/Division File/NDA 21-529

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Product Quality Microbiology Review
Review for HFD-580

11 February 2004

NDA: 21-529

Drug Product Name
   Proprietary: Implanon™ 68 mg
   Non-proprietary: etonorgestrel subdermal implant
   Drug Product Classification: Contraceptive

Review Number: 1

Subject of this Review
   Submission Date: 30 September 2003
   Receipt Date: 1 October 2003
   Consult Date: 28 November 2003
   Date Assigned for Review: 12 January 2004

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

Applicant/Sponsor
   Name: Organon
   Address: 375 Mt. Pleasant Avenue, West Orange, NJ 07052
   Representative: Edwina Muir
   Telephone: (973) 325-4540

Name of Reviewer: Paul Stinavage, Ph.D.

Conclusion: The application 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: N.V. Organon, Molenstraat 110, 5342 CC Oss, The Netherlands

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 68 mg of etonogestrel

5. STERILIZATION METHOD(S): b(4)

6. PHARMACOLOGICAL CATEGORY: contraceptive

B. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS: The product undergoes sterilization in blister packaging b(4)

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval on the basis of sterility assurance.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The packaged product is b(4)

B. Brief Description of Microbiology Deficiencies -

C. Assessment of Risk Due to Microbiology Deficiencies -

III. Administrative

A. Reviewer’s Signature

B. Endorsement Block
   P. Stinavage
   P. Cooney

C. CC Block
   cc:
   Original NDA 21-529
   HFD- 580/Division File/NDA 21-529

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/s/
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Paul Stinavage
2/11/04 11:11:50 AM
MICROBIOLOGIST
Implant.

sterilization. b(4)

Peter Cooney
2/11/04 03:06:19 PM
MICROBIOLOGIST