

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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. **b(4)**

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. **b(4)**

filename: n21529r2.doc

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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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 Draft Labeling

 Deliberative Process

Withheld Track Number: Microbiology-

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

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2. SUPPLEMENT PROVIDES FOR: N/A
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Oss, The Netherlands
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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)

filename: n21529.doc

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Executive Summary**I. Recommendations**

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

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 Q Deliberative Process

Withheld Track Number: Microbiology-

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this page is the manifestation of the electronic signature.**

/s/

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

sterilization.

b(4)

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