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RESEARCH**

*APPLICATION NUMBER:*

**203159Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

23 MAR 2012

**NDA:** 203-159/N-000

**Drug Product Name**

**Proprietary:** Skyla (proposed)

**Non-proprietary:** Levonorgestrel-releasing intrauterine system

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Submit	Received	Review Request	Assigned to Reviewer
09 DEC 2011	09 DEC 2011	31 JAN 2012	03 FEB 2012

**Applicant/Sponsor**

**Name:** Bayer HealthCare Pharmaceuticals, Inc.

**Address:** PO Box 1000  
Montville, NJ 07045-1000

**Representative:** Jo-Ann Ruane

**Telephone:** 973-487-2343

**Name of Reviewer:** Jessica G. Cole, PhD

**Conclusion:** Recommended for approval.

## Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** New drug product
3. **MANUFACTURING SITE:** The drug product is manufactured at Bayer Oy, Turku, Pansiontie 47, 20210 Turku, Finland and sterilized at Bayer Oy (b) (4)
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Intrauterine device with a core for extended drug release
  - 13.5 mg levonorgestrel/device and a release rate of ~10 µg/day in weeks 3-4
5. **METHOD(S) OF STERILIZATION:** (b) (4) ethylene oxide
6. **PHARMACOLOGICAL CATEGORY:** Prevention of pregnancy for up to 3 years
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** This submission was in the eCTD format and the drug product is similar to Mirena, which was approved under NDA 21-225.

**filename:** N203159R1.doc

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**Executive Summary****I. Recommendations**

- A. **Recommendation on Approvability** – This application is recommended for approval on the basis of product quality microbiology.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

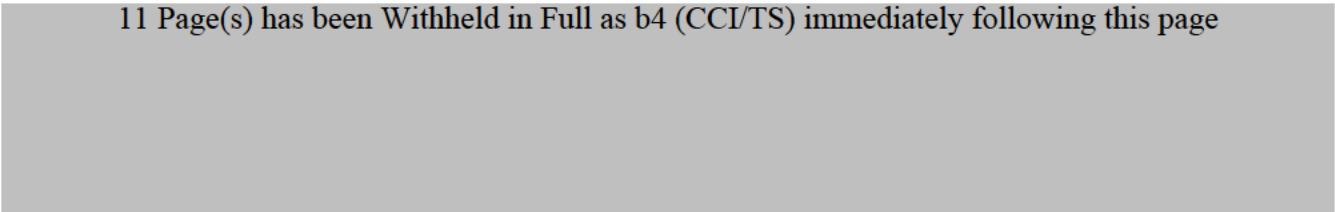
**II. Summary of Microbiology Assessments**

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is (b) (4) sterilized with ethylene oxide gas (b) (4)
- B. **Brief Description of Microbiology Deficiencies** – Not applicable.
- C. **Assessment of Risk Due to Microbiology Deficiencies** - Not applicable.

**III. Administrative**

- A. **Reviewer's Signature** \_\_\_\_\_  
Jessica G. Cole, PhD
- B. **Endorsement Block** \_\_\_\_\_  
John Metcalfe, PhD  
Senior Microbiology Reviewer
- C. **CC Block**  
N/A

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JESSICA COLE  
03/26/2012

JOHN W METCALFE  
03/26/2012  
I concur.