# CENTER FOR DRUG EVALUATION AND 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

# 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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/s/

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JESSICA COLE
03/26/2012

JOHN W METCALFE
03/26/2012
I concur.