

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206229Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

21 January 2015

NDA: 206-229/N000

Drug Product Name

Proprietary:

(b) (4)

Non-proprietary: Levonorgestrel Releasing Intrauterine System

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
29 April 2014	30 April 2014	2 May 2014	16 May 2014
29 July 2014	31 July 2014	NA	NA

Submission History (for 2nd Reviews or higher) – NA

Applicant/Sponsor

Name: Medicines 360

Address: 353 Sacramento Street Suite 900
San Francisco, CA 94111

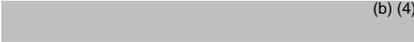
Representative: Victoria Hale, Ph.D.

Telephone: (415) 951-8700

Name of Reviewer: Denise A. Miller

Conclusion: Recommended for approval from a quality microbiology perspective.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** New drug application
 - 2. SUBMISSION PROVIDES FOR:** The manufacture of an intrauterine contraceptive device.
 - 3. MANUFACTURING SITE:**
Odyssea Pharma
Rue du travail, 16
B-4460 Grace-Hollogne, Belgium
 (b) (4)
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Dosage Form: Intrauterine device
 - Route of Administration: Intrauterine
 - Strength/Potency: 52 mg/device
 - 5. METHOD(S) OF STERILIZATION:**  (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Intrauterine contraception  (b) (4)
- B. SUPPORTING/RELATED DOCUMENTS:** NA
- C. REMARKS:**
The 74 day letter included a request for the method suitability study of the sterility test. The sponsor responded on 31 July 2014 and is discussed in the appropriate section of this review.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** - Recommended for approval from a quality microbiology perspective.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** - NA

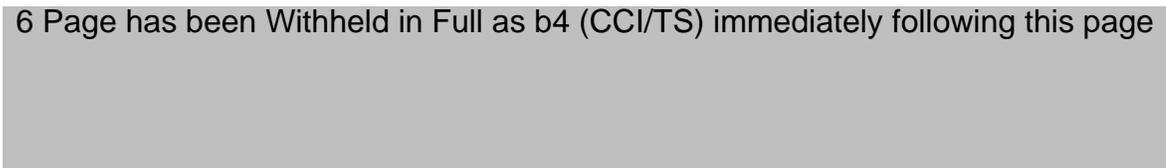
II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is assembled and [REDACTED] (b) (4).
- B. Brief Description of Microbiology Deficiencies** – No quality microbiology deficiencies were identified in the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies** – NA
- D. Contains Potential Precedent Decision(s)**- Yes No

III. Administrative

- A. Reviewer's Signature** _____
Denise A. Miller
Microbiologist, OPF/DMA/Branch II
- B. Endorsement Block** _____
Neal J. Sweeney, Ph.D.
Sr. Microbiologist, OPF/DMA/Branch II
- C. CC Block**
N/A

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/s/

DENISE A MILLER
01/23/2015

NEAL J SWEENEY
01/23/2015
I concur.