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

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<td>29 July 2014</td>
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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

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: [Redacted]

6. PHARMACOLOGICAL CATEGORY: Intrauterine contraception [Redacted]

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 [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.