

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205437Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

22 NOV 2013

NDA: 205437

Drug Product Name

Proprietary: Otezla (proposed)

Non-proprietary: Apremilast tablets

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
20 MAR 2013	21 MAR 2013	01 NOV 2013	04 NOV 2013
20 NOV 2013	21 NOV 2013	21 NOV 2013	21 NOV 2013
22 NOV 2013	22 NOV 2013	22 NOV 2013	22 NOV 2013

Applicant/Sponsor

Name: Celgene Corporation

Address: 86 Morris Avenue, Summit NJ 07901




Representative: Randall Stevens, MD

Telephone: (732-652-6592)

Name of Reviewer: Neal J. Sweeney, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Type 1, NME, Original NDA
 2. **SUBMISSION PROVIDES FOR:** Marketing of new drug product
 3. **MANUFACTURING SITES:**
Celgene International Sarl, Route de Perreux 1, 2017 Boudry, Switzerland
 (b) (4)
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Non-sterile oral dose Apremilast film-coated tablets, 10 mg, 20 mg, and 30 mg
 5. **METHOD(S) OF STERILIZATION:** N/A (non-sterile tablets)
 6. **PHARMACOLOGICAL CATEGORY:** Apremilast is a small-molecule inhibitor of phosphodiesterase 4 (PDE4), and proposed indication is for treatment of active psoriatic arthritis.
- B. **SUPPORTING/RELATED DOCUMENTS:**  (b) (4)
- C. **REMARKS:**  (b) (4)

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** - Recommended for Approval.
- 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** – Non-sterile tablet manufacturing utilizing (b) (4).
- B. Brief Description of Microbiology Deficiencies** – Based upon the information provided, no microbiology deficiencies were identified.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable
- D. Contains Potential Precedent Decision(s)**- Yes No
(If yes, provide a brief description and a reference to the page where the precedent is discussed in depth)

III. Administrative

- A. Reviewer's Signature** _____
Neal J. Sweeney, Ph.D.
- B. Endorsement Block** _____
Bryan S. Riley, Ph.D. Acting Team Leader
- 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.

/s/

NEAL J SWEENEY
11/25/2013

BRYAN S RILEY
11/25/2013
I concur.