CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-880

CHEMISTRY REVIEW(S)

NDA 21-880
Revlimid™
(Lenalidomide)

Celgene Corporation

Haripada Sarker, Ph.D.
HFD-150 Division of Oncology

Table of Contents

Chemistry Review Data Sheet

1. NDA 21-880

2. REVIEW #1:

3. REVIEW DATE: 12-05-2005

4. REVIEWER: Haripada Sarker, Ph.D.

6. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
IND 60,100	March 31, 2000

1. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original (RRZ-001) -rolling	December 22, 2004
Amendment (N-000) - Labeling	April 7, 2005
Amendment (N-000-BC) – DP stability and spec. update	May 17, 2005
Amendment (N-000-BC) – DP dissolution update	August 25, 2005
Amendment (N-000-BC) – DS and DP Stability	September 30, 2005
Amendment (N-000)C – DP Labeling	October 27, 2005

7. NAME & ADDRESS OF APPLICANT:

Name:	Celgene Corporation
Address:	86 Morris Avenue Summit, NJ 07901
Representative:	Gretchen Toolan

Telephone: 908-673-9551

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Revlimid™
b) Non-Proprietary Name: Lenalidomide
c) Code Name/#: CC-5013, CDC-501, Revlimid
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 1
- Submission Priority: P

e) Proposed Trade Name: Revlimid™

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: Transfusion-Dependent Anemia Due to Low- or Intermediate-1-Risk Myelodysplastic Syndroms Associated with a Deletion 5q Cytogenetic Abnormality.

11. DOSAGE FORM: Capsule

12. STRENGTH/POTENCY: 5 mg and 10 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: _X_ Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Structure:

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