

**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**



N21-880 CR#1

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# 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

IND 60,100

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—  
—Document Date

March 31, 2000

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## 1. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Original (RRZ-001) -rolling

Amendment (N-000) - Labeling

Amendment (N-000-BC) – DP stability and spec. update

Amendment (N-000-BC) – DP dissolution update

Amendment (N-000-BC) – DS and DP Stability

Amendment (N-000)C – DP Labeling

Document Date

December 22, 2004

April 7, 2005

May 17, 2005

August 25, 2005

September 30, 2005

October 27, 2005

## 7. NAME & ADDRESS OF APPLICANT:

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

N21-880 CR#1

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:  Rx  OTC

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

SPOTS product – Form Completed

Not a SPOTS product

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

Structure:

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