# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 214120Orig1s000

# PROPRIETARY NAME REVIEW(S)

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

| | |
|---|---|
| **Date of This Review:** | July 30, 2020 |
| **Application Type and Number:** | NDA 214120 |
| **Product Name and Strength:** | Onureg (azacitidine) tablets, 200 mg and 300 mg |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Celgene Corporation (Celgene) |
| **Panorama #:** | 2020-40796300 |
| **DMEPA Safety Evaluator:** | Ariane O. Conrad, PharmD, BCACP, CDCES |
| **DMEPA Team Leader:** | Hina Mehta, PharmD |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Onureg, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Celgene submitted an external name study[a], conducted by (b) (4) which was reviewed during our previous evaluation of this proposed proprietary name under IND 074618.[b] Of note, Celgene's June 19, 2020 proprietary name submission refers to the data submitted to their March 3, 2020 proprietary name submission for Onureg.

## 1.1 REGULATORY HISTORY

Celgene submitted the proposed proprietary name Onureg on September 26, 2014 under IND 074618. DMEPA found the name to be acceptable on March 19, 2015 under the IND.[b] Thus, Celgene submitted the name Onureg for review under NDA 214120 on March 3, 2020.

On April 30, 2020, Celgene submitted a request to withdraw the proposed name Onureg and submitted the name (b) (4) *** for review under NDA 214120. Subsequently, on June 19, 2020, Celgene submitted a request to withdraw the proposed name (b) (4) *** and resubmitted the name Onureg for review.

## 1.2 PRODUCT INFORMATION

The June 19, 2020 proprietary name submission refers to the March 3, 2020 proprietary name submission for product information. The following product information is provided in the proprietary name and labeling submissions received on March 3, 2020, and response to information request received July 22, 2020.

- Intended Pronunciation: OWN-yew-reg
- Nonproprietary Name: azacitidine
- Indication of Use (b) (4)
- Route of Administration: oral
- Dosage Form: tablets

---

[a] Request for Proprietary Name Review for azacytidine for oral administration (NDA 214120). Summit (NJ): Celgene Corporation; 2020 Mar 3. Available from: \\cdsesub1\evsprod\nda214120\0001\m1\us\onureg.pdf.

[b] Rutledge M. Proprietary Name Review for Onureg (IND 074618). Silver Spring (MD). FDA, CDER, OSE, DMEPA (US). 2015 Mar 19. Panorama No.: 2014-36965.

- Strength: 200 mg and 300 mg[c]
- Dose and Frequency: (b) (4) 300 mg once a day on Day 1 through 14 of a 28-day treatment cycle. Dose may be adjusted to 200 mg once a day for adverse reactions.
- How Supplied: (b) (4) 14-count bottles
- Storage: store 68°F - 77°F (20°C -25°C). The proposed shelf life is (b) (4) months.

## 2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Onureg.

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Onureg would not misbrand the proposed product per their July 9, 2020 email. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematologic Malignancies 1 (DHM 1) concurred with the findings of OPDP's assessment for Onureg.

### 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Onureg.

#### *2.2.1 United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name[d].

#### *2.2.2 Components of the Proposed Proprietary Name*

Celgene indicated in their submission that the proposed proprietary name, Onureg, is "not derived from any one particular concept" in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

#### *2.2.3 Comments from Other Review Disciplines at Initial Review*

In response to the OSE July 9, 2020 email, the Division of Hematologic Malignancies 1 (DHM 1) did not forward any comments or concerns relating to Onureg at the initial phase of the review.

#### *2.2.4 FDA Name Simulation Studies*

Eighty-nine practitioners participated in DMEPA's prescription studies for Onureg. The responses did not overlap with any currently marketed products nor did the responses sound or

[c] We note that there is a change in product characteristics as Celgene proposes two tablet strengths (200 mg and 300 mg) in the current submission. In the September 26, 2014 request for proprietary name review of Onureg, Celgene proposed tablet strengths of 100 mg, 150 mg, 200 mg, and 300 mg.

[d] USAN stem search conducted on June 22, 2020.

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.