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RESEARCH**

APPLICATION NUMBER:

206545Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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: March 4, 2014

Application Type and Number: NDA 206545

Product Name and Strength: Zydelig (Idelalisib) Tablets
100 mg, 150 mg

Product Type: Single Ingredient

Rx or OTC: Rx

Applicant/Sponsor Name: Gilead Sciences, Inc

Submission Date: January 6, 2014

Panorama #: 2014-6793

DMEPA Primary Reviewer: Michelle Rutledge, PharmD

DMEPA Team Leader: Yelena Maslov, PharmD

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1 INTRODUCTION

The proposed proprietary name, Zydelig, was found acceptable in OSE Review# 2013-776, dated September 19, 2013 under IND 101254 and in OSE Memorandum# 2013-2086, dated September 30, 2013 under NDA 205858. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Zydelig, is acceptable from both a promotional and safety perspective under the NDA 206545.

If you have further questions or need clarifications, please contact Sonny Saini, OSE project manager, at 301-796-0532.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Zydelig, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your January 6, 2014 submission are altered, the name must be resubmitted for review.

REFERENCES

1. OSE Review# 2013-776: Proprietary Name Review for Zydelig (Idelalisib), September 19, 2013.
2. OSE Memorandum# 2013-2086: Proprietary Name Memorandum for Zydelig (Idelalisib), September 30, 2013

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/s/

MICHELLE K RUTLEDGE
03/10/2014

YELENA L MASLOV
03/11/2014