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RESEARCH**

APPLICATION NUMBER:

206256Orig1s000

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)

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Date of This Review:	February 28, 2014
Application Type and Number:	NDA 206256
Product Name and Strength:	Beleodaq (Belinostat) for Injection, 500 mg/vial
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc
Submission Date:	February 25, 2014
Panorama #:	2014-16986
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

The proposed proprietary name, Beleodaq, was found acceptable in OSE Review# #2013-1967, dated November 4, 2013 under IND 070789. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Beleodaq, is acceptable from both a promotional and safety perspective under the NDA 206256.

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, Beleodaq, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your February 25, 2014 submission are altered, the name must be resubmitted for review.

2 REFERENCES

- 1. *OSE Review# 2013-1967: Proprietary Name Review for Beleodaq (Belinostat), November 4, 2013.***

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/s/

TINGTING N GAO
02/28/2014

YELENA L MASLOV
03/04/2014