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RESEARCH**

APPLICATION NUMBER:

206192Orig1s000

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 5, 2015
Application Type and Number:	NDA 206192
Product Name and Strength:	Cotellic (cobimetinib) Tablets, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Genentech, Inc.
Submission Date:	January 6, 2015
Panorama #:	2015-46941
DMEPA Primary Reviewer:	Otto L. Townsend, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Chu, PharmD

1 INTRODUCTION

The proposed proprietary name, Cotellic, was found acceptable in OSE Review# 2014-25757, dated October 8, 2014 under IND 109307.¹ This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Cotellic, is acceptable from both a promotional and safety perspective under the NDA 206192.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 6, 2015 submission are altered, the name must be resubmitted for review.

¹ Townsend, O. Proprietary Name Review for Cotellic (cobimetinib) (IND 109307). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 OCT 08. 30 p. OSE RCM No.: 2014-25757.

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/s/

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02/05/2015

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