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APPLICATION NUMBER:

205832Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW 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:	July 2, 2014
Application Type and Number:	NDA 205832
Product Name and Strength:	Ofev (nintedanib) Capsules, 100 mg, 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals, Inc.
Submission Date:	June 6, 2014
Panorama #:	2014-25552
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

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1 INTRODUCTION

The proposed proprietary name, Ofev, was found acceptable in OSE Review# 2013-16346, dated April 4, 2014 under IND 074683. We note that product characteristics are the same for NDA 205832 currently under review as the IND. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Ofev, is acceptable from both a promotional and safety perspective under the NDA 205832.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904.

2 COMMENTS TO THE APPLICANT

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

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

REFERENCES

1. McMillan T, Proprietary name review for Ofev (IND 074683). 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); 2014-04-17. OSE RCM No.: 2013-16346

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/s/

TERESA S MCMILLAN
07/02/2014

LUBNA A MERCHANT
07/03/2014