CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204063Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	January 16, 2013
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
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Drug Name and Strengths:	Tecfidera (Dimethyl Fumarate) Delayed-release Capsules 120 mg and 240 mg
Application Type/Number:	NDA 204063
Applicant/Sponsor:	Biogen Idec
OSE RCM #:	2012-2508

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Tecfidera, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Dimethyl fumarate is a New Molecular Entity (NME). This product was reviewed under IND 073061 with the proposed proprietary name, (b) (4), which was found acceptable in OSE Review # 2009-2403 dated April 28, 2010. The Applicant subsequently requested to withdraw the name, (b) (4) and requested review of the proposed proprietary name, (b) (4) In OSE Review # 2010-2674 dated May 26, 2011, the Division of Medication Error Prevention and Analysis (DMEPA) found the name unacceptable (b) (4) . On February 29, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) under NDA 204063. In OSE Review # 2012-542 dated May 23, 2012, DMEPA found the name unacceptabl (b) (4) On May 30, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) In OSE Review # 2012-1263, DMEPA found the name unacceptable (b) (4) On August 29, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) On October 19, 2012, the OSE Project Manager e-mailed the Applicant stating that DMEPA identified a foreign produc (b) (4) On October 24, 2012, the Applicant withdrew the proposed proprietary name (b) (4)

On October 24, 2012, the Applicant submitted a request for the review of the proposed proprietary name, Tecfidera.

The labels and labeling for Dimethyl Fumarate were reviewed under separate cover (OSE Review # 2012-530).

1.2 PRODUCT INFORMATION

The following product information is provided in the October 24, 2012 proprietary name submission.

- Active Ingredient: Dimethyl Fumarate
- Indication of Use: Treatment of patients with relapsing multiple sclerosis (b) (4)

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- Route of Administration: Oral
- Dosage Form: Delayed-release capsules
- Strength: 120 mg, 240 mg
- Dose and Frequency: 120 mg by mouth twice daily for 7 days, then 240 mg by mouth twice daily; temporary dose reduction to 120 mg twice daily may reduce occurrence of flushing and GI side effects – within 1 month, the recommended dose of 240 mg twice daily should be resumed
- How Supplied:
  - (b) (4)
  - 30 day starter pack (14-count bottle 120 mg capsules and 46-count bottle 240 mg capsules packaged in the same carton): retail and professional sample
  - 120 mg capsules
    - 14-count bottle: retail and professional sample
  - 240 mg capsules
    - 14-count bottle: retail and professional sample
    - 60-count bottle: retail
- Storage: Store at 15°C to 30 °C (59°F to 86 °F). Protect capsules from light; Once opened, discard bottles after 90 days
- Container and Closure Systems: HDPE bottles sealed with an aluminum foil induction seal and white polypropylene (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

The November 28, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

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