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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

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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

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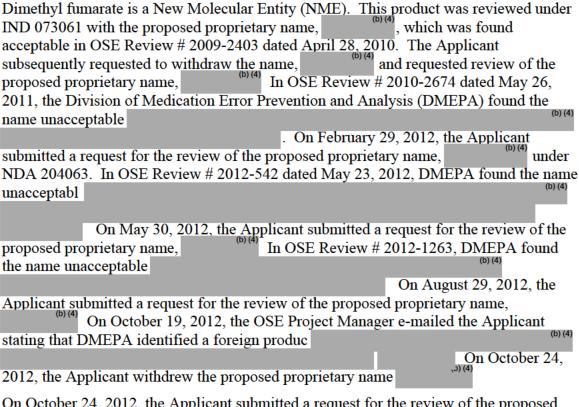
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1 INTRODUCTION

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



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 (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:
 - O (6) (4)
 - o 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
 - o 120 mg capsules
 - 14-count bottle: retail and professional sample
 - o 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

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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