CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 204063/S-10

Trade Name: Tecfidera

Generic Name: Dimethyl fumarate

Sponsor: Biogen IDEC Inc.

Approval Date: December 03, 2014

Indications: For the treatment of patients with relapsing forms of multiple sclerosis.

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NDA 204063/S-10

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NDA 204063/S-10

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204063/S-003, S-008, and S-010 **SUPPLEMENT APPROVAL**

Biogen Idec
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142

Dear Dr. Cohen:

Please refer to your Supplemental New Drug Applications (sNDA):

Application	Product Name	Submitted on:	Received on:
NDA 204063/S-003	Tecfidera (dimethyl fumarate)	January 31, 2014	February 3, 2014
This supplement, submitted as a "Prior Approval supplement," proposes:			
The (b) (4) temporary dose reduction to manage flushing and gastrointestinal side effects associated with Tecfidera treatment.			

Application	Product Name	Submitted on:	Received on:
NDA 204063/S-008	Tecfidera (dimethyl fumarate)	July 28, 2014	July 28, 2014
This supplement, submitted as a "Prior Approval supplement," proposes changes to:			
Highlights and Section 4: Contraindication for patients with known hypersensitivity to dimethyl fumarate or to any of the excipients of Tecfidera Section 5.1: Hypersensitivity reactions (section added) Section 8.1: Pregnancy registry phone number updated and website added			

Application	Product Name	Submitted on:	Received on:
NDA 204063/S-010	Tecfidera (dimethyl fumarate)	November 6, 2014	November 6, 2014
This supplement, submitted as a "Prior Approval supplement," proposes changes to:			
Highlights: Warnings and Precautions Section 2.1 – Dosing and Administration Section 5.2 – Progressive Multifocal Leukoencephalopathy (section added) Section 5.3 – Lymphopenia Section 17 – Patient Counseling Information Patient Information			

We also acknowledge receipt of your amendments to NDA 204063/S-003 dated February 21, 2014 and November 19, 2014; NDA 204063/S-008 dated August 25, 2014, October 17, 2014, October 23, 2014, and October 29, 2014; and NDA 204063/S-010 dated November 7, 2014, November 25, 2014, November 26, 2014, and December 3, 2014.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

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