



NDA 211855/S-017

APPROVAL LETTER

Biogen Inc.
Attention: Priya Singhal, MD, MPH
Executive Vice President, Head of Development
225 Binney Street
Cambridge, MA 02142

Dear Dr. Singhal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 15, 2024, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vumerity (diroximel fumarate) capsule, delayed release.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the following changes.

- Addition of [REDACTED] ^{(b) (4)} [FEI Number [REDACTED] ^{(b) (4)}] as an alternate drug product packaging (primary and secondary) and labeling site.
- Addition of [REDACTED] ^{(b) (4)} an alternate supplier of primary packaging components (200 cc HDPE bottles and [REDACTED] ^{(b) (4)} closure).
- Removal of the 106-count bottle (200 cc HDPE) packaging configuration from the market.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below.

Carton and Container Labels

1. Remove the statement “maintenance dose bottle” from the container and carton labeling.

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 Prescribing

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Silver Spring, MD 20993
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Information and Patient Package Insert) with the addition of any labeling changes in pending “Changes Being Effectuated” (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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via 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 this supplemental application, 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).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labeling that are identical to the submitted carton and container labeling, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 211855/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Crich, Ph.D.
Senior Quality Pharmaceutical Assessor

For:

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Content of Labeling
- o Prescribing Information
- o Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE Z CRICH
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