



NDA 211855/S-011

**APPROVAL LETTER**

Biogen Inc  
Attention: Priya Singhal  
Senior Vice President, Global Safety and Regulatory Sciences  
225 Binney Street  
Cambridge, MA 02142

Dear Ms. Singhal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 19, 2022, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vumerity (diroximel fumarate) Delayed-release Capsules.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the registration of additional Pack Size of 14-count bottle as physicians' samples.

**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.

**CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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-011.**” 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.

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If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, Ph.D.  
Branch Chief, Branch 3  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Gurpreet  
Gill Sangha

Digitally signed by Gurpreet Gill Sangha

Date: 11/16/2022 11:42:33AM

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