



ANDA 218596

**ANDA APPROVAL**

Zydus Pharmaceuticals (USA) Inc.  
U.S. Agent for Zydus Worldwide DMCC  
Attention: Srinivas Gurram  
Senior Vice President

Dear Srinivas Gurram:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 31, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Diroximel Fumarate Delayed-Release Capsules, 231 mg.

Reference is also made to the tentative approval letter issued by this office on July 9, 2024, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Diroximel Fumarate Delayed-Release Capsules, 231 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vumerity Delayed-Release Capsules, 231 mg, of Biogen Inc. (Biogen) NDA - 211855.

Reference is also made to FDA’s Competitive Generic Therapy Designation – Grant letter dated May 16, 2023.

The RLD upon which you have based your ANDA, Biogen’s Vumerity Delayed-Release Capsules, 231 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency’s publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
8,669,281 (the '281 patent)	October 29, 2033
9,090,558 (the '558 patent)	September 20, 2033
10,080,733 (the '733 patent)	September 20, 2033

Your ANDA contains paragraph IV certifications to each of the patents, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Diroximel Fumarate Delayed-Release Capsules, 231 mg, under this ANDA. You have notified the Agency that Zydus Worldwide DMCC (Zydus) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Zydus for infringement of the '281, '558 and '733 patents in the United States District Court for the District of Delaware [Biogen Inc., Biogen Swiss Manufacturing GMBH, and Alkermes Pharma Ireland Limited v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, Civil Action No. 23-00732]. You have also notified the Agency that this case was dismissed.

We note that Zydus was granted a Competitive Generic Therapy (CGT) designation for Diroximel Fumarate Delayed-Release Capsules, 231 mg. However, as noted in the May 16, 2023, CGT Designation – Grant Letter, your Diroximel Fumarate Delayed-Release Capsules, 231 mg, is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

### **COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

**REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Kendra S. Stewart, R.Ph., Pharm.D.  
CAPT, United States Public Health Service  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Catherine  
Poole

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