



ANDA 208443

**ANDA APPROVAL**

Actavis Laboratories FL, Inc.  
2945 West Corporate Lakes Blvd.  
Suite B  
Weston, FL 33331  
Attention: Alberto Rivalta  
Senior Director, Regulatory Affairs

Dear Alberto Rivalta:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 27, 2015, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Fidaxomicin Tablets, 200 mg.

Reference is also made to the tentative approval letter issued by this office on October 10, 2023, 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 Fidaxomicin Tablets, 200 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Difucid Tablets, 200 mg, of Cubist Pharmaceuticals LLC (Cubist).

The RLD upon which you have based your ANDA, Cubist's Difucid Tablets, 200 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) 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>
7,378,508 (the '508 patent)	January 31, 2028
7,863,249 (the '249 patent)	January 31, 2028
7,906,489 (the '489 patent)	September 4, 2027
8,859,510 (the '510 patent)	January 31, 2028

With respect to: 1) the '508 and '249 patents and 2) the '489 and '510 patents (excluding those portions pertaining to the use code U-2741 (b) (4) your ANDA contains paragraph IV certifications, 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 Fidaxomicin Tablets, 200 mg, under this ANDA. You have notified the Agency that Actavis Laboratories FL, Inc. (Actavis) 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 Actavis for infringement of the '508, '249, '489, and '510 patents in the United States District Court for the District of New Jersey [Merck Sharp & Dohme Corp., Cubist Pharmaceuticals LLC, Optimer Pharmaceuticals LLC, and MSD International GMBH v. Actavis Laboratories FL, Inc., Civil Action No. 15-06541 (consolidated)]. You have also notified the Agency that this case was dismissed.

With respect to portions of the '489 and '510 patents pertaining to the use code U-2741 (b) (4), your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Actavis was a first ANDA applicant for Fidaxomicin Tablets, 200 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Actavis may be eligible for 180 days of generic drug exclusivity for Fidaxomicin Tablets, 200 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Actavis failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Actavis' eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Actavis begins commercial marketing of Fidaxomicin Tablets, 200 mg, or (b) at any time prior to the expiration of the '508, '249, '489, and '510 patents if Actavis has not begun commercial marketing. Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

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 Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Catherine  
Poole

Digitally signed by Catherine Poole

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