ANDA 219687

**ANDA TENTATIVE APPROVAL**

Mylan Pharmaceuticals Inc.
Attention: Kristen McElwayne
Senior Director, Regulatory Affairs

Dear Kristen McElwayne:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 2, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Rifaximin Tablets, 550 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

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. We have determined your Rifaximin Tablets, 550 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xifaxan Tablets, 550 mg, of Salix Pharmaceuticals, Inc. (Salix) NDA - 021361.

However, we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The RLD upon which you have based your ANDA, Salix's Xifaxan Tablets, 550 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.S. Patent Number | Expiration Date |
|---|---|
| 8,193,196 (the '196 patent) | September 2, 2027 |
| 8,309,569 (the '569 patent) | July 18, 2029 |
| 8,518,949 (the '949 patent) | February 27, 2026 |

| | |
|---|---|
| 8,642,573 (the '573 patent) | October 2, 2029 |
| 8,741,904 (the '904 patent) | February 27, 2026 |
| 8,829,017 (the '017 patent) | July 24, 2029 |
| 8,946,252 (the '252 patent) | July 24, 2029 |
| 8,969,398 (the '398 patent) | October 2, 2029 |
| 9,271,968 (the '968 patent) | February 27, 2026 |
| 9,421,195 (the '195 patent) | July 24, 2029 |
| 9,629,828 (the '9828 patent) | July 24, 2029 |
| 10,314,828 (the '4828 patent) | July 24, 2029 |
| 10,335,397 (the '397 patent) | July 24, 2029 |
| 10,456,384 (the '384 patent) | February 26, 2029 |
| 10,703,763 (the '763 patent) | February 27, 2026 |
| 10,709,694 (the '694 patent) | July 24, 2029 |
| 10,765,667 (the '667 patent) | February 26, 2029 |
| 11,564,912 (the '912 patent) | February 26, 2029 |
| 11,779,571 (the '571 patent) | February 26, 2029 |

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 Rifaximin Tablets, 550 mg, under this ANDA. You have notified the Agency that Mylan Pharmaceuticals Inc. (Mylan) 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 Mylan for infringement of the '196, '912, and '571 patents in the United States District Court for the Northern District of West Virginia [Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.P.A. and Bausch Health Ireland Ltd. v. Mylan Pharmaceuticals Inc., Civil Action No. 25-00024]. You have also notified the Agency that this case was dismissed.

However, we are unable to grant final approval to your ANDA at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially

complete ANDA providing for Rifaximin Tablets, 550 mg, and containing a paragraph IV certification. Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

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.

## REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, if your ANDA receives final approval, it 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.

## RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available Agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact CDR Daniil Marchuk, Regulatory Project Manager, at (240) 402 - 4322.

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

Digitally signed by Catherine Poole
Date: 1/07/2026 10:27:38AM
GUID: 5407887a000a1c0c26055eafb8e3258a