



ANDA 218089

ANDA TENTATIVE APPROVAL

Lifestar Pharma LLC
U.S. Agent for Mankind Pharma Limited
1200 Macarthur Blvd.
Mahwah, NJ 07430
Attention: Parimal Upadhyay
Senior Vice President

Dear Parimal Upadhyay:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 9, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Revefenacin Inhalation Solution, 175 mcg/3 mL Unit-Dose Vial.

Reference is also made to the complete response letter issued by this office on August 28, 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. We have determined your Revefenacin Inhalation Solution, 175 mcg/3 mL Unit-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Yupelri Inhalation Solution, 175 mcg/3 mL, of Mylan Ireland Limited (Mylan) NDA - 210598.

However, we are unable to grant final approval to your ANDA at this time because of the patent 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. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C Act.

The RLD upon which you have based your ANDA, Mylan's Yupelri Inhalation Solution, 175 mcg/3 mL, 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>
7,288,657 (the '657 patent)	October 31, 2028
7,491,736 (the '736 patent)	March 10, 2025
7,521,041 (the '041 patent)	March 10, 2025
7,550,595 (the '595 patent)	March 10, 2025
7,585,879 (the '879 patent)	March 10, 2025
7,910,608 (the '608 patent)	March 10, 2025
8,034,946 (the '946 patent)	March 10, 2025
8,053,448 (the '448 patent)	March 10, 2025
8,273,894 (the '894 patent)	March 10, 2025
8,541,451 (the '451 patent)	August 25, 2031
9,765,028 (the '028 patent)	July 14, 2030
10,106,503 (the '503 patent)	March 10, 2025
10,343,995 (the '995 patent)	March 10, 2025
10,550,081 (the '081 patent)	July 14, 2030
11,008,289 (the '289 patent)	July 14, 2030
11,247,969 (the '969 patent)	March 10, 2025
11,484,531 (the '531 patent)	October 23, 2029
11,691,948 (the '948 patent)	July 14, 2030
11,858,898 (the '898 patent)	July 14, 2030
12,048,692 (the '692 patent)	August 29, 2039

With respect to the '657, '736, '041, '595, '879, '608, '946, '448, '894, '503, '995 and '969 patents, your ANDA contains paragraph III certifications to each of the patents under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Mankind Pharma Limited (Mankind) will not market Revefenacin Inhalation Solution, 175 mcg/3 mL Unit-Dose

Vial prior to the expiration of the patents. Therefore, final approval of your ANDA may not be granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until the '657 patent has expired, currently October 31, 2028.

Your ANDA contains paragraph IV certifications to the '451, '028, '081, '289, '531, '948, '898 and '692 patents¹ 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 Revefenacin Inhalation Solution, 175 mcg/3 mL Unit-Dose Vial, under this ANDA. You have notified the Agency that Mankind 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 Mankind for infringement of the '451, '028, '081, '289 and '531 patents in the United States District Court for the District of New Jersey [Theravance Biopharma R&D IP, LLC, Theravance Biopharma US, Inc., Theravance Biopharma Ireland Limited, Mylan Ireland Limited, and Mylan Specialty L.P. v. Mankind Pharma Limited et al., Civil Action No. 23-00926].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 7.5-year period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,
 - b. the date the court decides² that the '451, '028, '081, '289 and '531 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act), or
 - c. the '451, '028, '081, '289, '531, '657, '736, '041, '595, '879, '608, '946, '448, '894, '503, '995 and '969 patents have expired, and
2. The Agency is assured there is no new information that would affect whether final approval should be granted.

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. Should you believe that there are grounds for issuing the final approval letter prior to October 31, 2028, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Tom Ching, Regulatory Project Manager, at (301) 796 - 8445.

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

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- ¹ The agency notes that the '948, '898 and '692 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.
- ² This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.



Catherine
Poole

Digitally signed by Catherine Poole

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