ANDA 218495

ANDA TENTATIVE APPROVAL

Novitium Pharma LLC
Attention: Muthusamy Shanmugam
Founder and President

Dear Muthusamy Shanmugam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 14, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Pitolisant Tablets, 4.45 mg and 17.8 mg.

Reference is also made to the complete response letter issued by this office on June 11, 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 Pitolisant Tablets, 4.45 mg and 17.8 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Wakix Tablets, 4.45 mg and 17.8 mg, of Harmony Biosciences Management, Inc. (Harmony) NDA 211150.

However, we are unable to grant final approval to your ANDA at this time because of the patent and exclusivity issues noted below. Therefore, the ANDA is **tentatively approved**.[1] 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, Harmony's Wakix Tablets, 4.45 mg and 17.8 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
8,207,197 (the '197 patent)	March 7, 2030
8,486,947 (the '947 patent)	September 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 Pitolisant Tablets, 4.45 mg and 17.8 mg, under this ANDA. You have notified the Agency that Novitium Pharma LLC (Novitium) 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 Novitium for infringement of the '197and '947 patents in the United States District Court for the District of Delaware [Harmony Biosciences, LLC, Bioprojet Societe Civile de Recherche, and Bioprojet Pharma SAS v. Novitium Pharma LLC, et al., Civil Action No. 23-01286 (consolidated)]. You have also notified the Agency that this case was dismissed.

However, because the statutory 45-day period associated with your March 6, 2026, paragraph IV notices, as described in section 505(j)(5)(B)(iii) of the FD&C Act, has not yet expired, final approval cannot be granted at this time.

The RLD upon which you have based your ANDA, Harmony's Wakix Tablets, 4.45 mg and 17.8 mg, is subject to periods of exclusivity. As noted in the Orange Book, the ODE-255, NPP, ODE-331, and ODE-489 exclusivities are scheduled to expire on, August 14, 2026, June 21, 2027, October 13, 2027, and June 21, 2031, respectively. Therefore, final approval cannot be granted until either the ODE-489 exclusivity has expired, June 21, 2031, or you provide a letter from Harmony that waives any unexpired period of exclusivity.

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 Tram Nguyen, Regulatory Project Manager, at (240) 402-1028.

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

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[1] With this Tentative Approval letter, the Agency informs you that FDA is continuing to evaluate whether one or more supplements to NDA No. 211150, which is the RLD cited as the Basis of Submission for this ANDA, is eligible for three-year exclusivity under section 505(c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(iii), and (j)(5)(F)(iv) of the FD&C Act. Upon making its decision, the Agency will identify any period of exclusivity for which NDA No. 211150 is eligible in the Orange Book. Please note that any determination that a supplement to NDA No. 211150 qualifies for exclusivity may affect the date on which your ANDA is eligible for Final Approval. Please also note that if you seek to omit any exclusivity-protected indication or aspect of labeling under 21 CFR 314.94(a)(8)(iv), FDA will need to evaluate the acceptability of your proposed labeling. FDA recommends that you request Final Approval in a manner consistent with recommendations in the *Guidance for Industry: ANDA Submissions-Amendments and Request for Final Approval to Tentatively Approved ANDAs* taking into account when you believe all barriers to final approval will be extinguished.

Paul
Levine

Digitally signed by Paul Levine
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