



ANDA 218654

ANDA TENTATIVE APPROVAL

Hetero USA, Inc.
U.S. Agent for Hetero Labs Limited Unit V
1035 Centennial Avenue
Piscataway, NJ 08854
Attention: Soma Raju Indukuri
Vice President, Regulatory Affairs

Dear Soma Raju Indukuri:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 20, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Solriamfetol Tablets, 75 mg and 150 mg.

Reference is also made to the complete response letter issued by this office on April 5, 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 Solriamfetol Tablets, 75 mg and 150 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Sunosi Tablets, 75 mg and 150 mg, of Axsome Malta Limited (Axsome) NDA - 211230.

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, Axsome's Sunosi Tablets, 75 mg and 150 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>
8,440,715 (the '715 patent)	June 11, 2031
8,877,806 (the '806 patent)	June 7, 2026
9,604,917 (the '917 patent)	June 7, 2026
10,195,151 (the '151 patent)	September 5, 2037
10,351,517 (the '517 patent)	June 7, 2026
10,512,609 (the '12609 patent)	September 5, 2037
10,912,754 (the '754 patent)	June 1, 2038
10,940,133 (the '133 patent)	March 19, 2040*
10,959,976 (the '976 patent)	June 1, 2038
11,160,779 (the '779 patent)	March 19, 2040
11,439,597 (the '597 patent)	September 5, 2037
11,560,354 (the '354 patent)	March 6, 2039
11,648,232 (the '232 patent)	June 1, 2038
11,753,368 (the '368 patent)	June 7, 2026
11,771,666 (the '666 patent)	December 30, 2042
11,771,667 (the '667 patent)	December 30, 2042
11,779,554 (the '554 patent)	December 30, 2042
11,793,776 (the '776 patent)	December 30, 2042
11,839,598 (the '598 patent)	March 19, 2040
11,839,599 (the '599 patent)	March 19, 2040
11,850,226 (the '226 patent)	March 19, 2040
11,850,227 (the '227 patent)	March 19, 2040

11,850,228 (the '228 patent)	March 19, 2040
11,857,528 (the '528 patent)	March 19, 2040
11,865,098 (the '098 patent)	June 1, 2038
11,872,203 (the '203 patent)	December 30, 2042
11,872,204 (the '204 patent)	December 30, 2042
11,969,404 (the '404 patent)	March 19, 2040
11,986,454 (the '454 patent)	March 19, 2040
11,986,455 (the '455 patent)	March 19, 2040
11,998,639 (the '639 patent)	September 5, 2037
12,005,036 (the '036 patent)	December 30, 2042
12,036,194 (the '194 patent)	December 30, 2042
12,064,411 (the '411 patent)	December 30, 2042
12,090,126 (the '126 patent)	December 30, 2042
12,102,609 (the '02609 patent)	December 30, 2042

* 75 mg strength only

With respect to the '806, '917, '517, and '368 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 Hetero Labs Limited Unit V (Hetero) will not market Solriamfetol Tablets, 75 mg and 150 mg 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 '806, '917, '517, and '368 patents have expired, currently June 7, 2026.

Your ANDA contains paragraph IV certifications to the '715, '151, '12609, '754, '133, '976, '779, '597, '354, '232, '666, '667, '554, '776, '598, '599, '226, '227, '228, '528, '098, '203, '204, '404, '454, '455, '639, '036, '194, '411, '126, and '02609 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 Solriamfetol Tablets, 75 mg and 150 mg, under this ANDA. You have notified the Agency that Hetero 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 Hetero for infringement of the '715,

'151, '12609, '754, '133, '976, '779, '597, '354, and '232 patents in the United States District Court for the District of New Jersey [Axsome Malta Ltd., and Axsome Therapeutics, Inc. v. Hetero Labs Limited Unit V et. al., Civil Action No. 23-20354].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 7.5-year period provided for in section 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,
 - b. the date the court decides² that the '715, '151, '12609, '597, '754, '976, '779, '133, '354, and '232 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 '806, '917, '517, '368, '715, '151, '12609, '597, '754, '976, '779, '133, '354, and '232 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.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Kim Brown, Regulatory Project Manager, at (301) 796 - 4292.

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

¹ The Agency notes that the '666, '667, '554, '776, '598, '599, '226, '227, '228, '528, '098, '203, '204, '404, '454, '455, '639, '036, '194, '411, '126, and '02609 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

Date: 12/11/2024 09:50:34AM

GUID: 5407887a000a1c0c26055eafb8e3258a