FDA U.S. FOOD & DRUG ADMINISTRATION

ANDA 218016

ANDA APPROVAL

Hikma Pharmaceuticals USA Inc.
Attention: Arpita Pal
Associate

Dear Arpita Pal:

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 approval letter issued on June 17, 2026. This corrected letter is being issued to clarify that the letter was missing information related to 180-day exclusivity. This letter supersedes our June 17, 2026, approval letter. The action date for the approval letter remains unchanged as June 17, 2026.

Reference is also made to the tentative approval letter issued by this office on November 19, 2024.

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 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 Ltd (Axsome) NDA - 211230.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated July 27, 2023.

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.S. Patent Number	Expiration Date
8,440,715 (the '715 patent)	June 11, 2031
10,195,151 (the '151 patent)	September 5, 2037
10,512,609 (the 12'609 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
11,771,666 (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
11,969,454 (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 2'609 patent)	December 30, 2042
12,194,016 (the '016 patent)	March 19, 2040
12,263,145 (the '145 patent)	December 30, 2042*
12,318,362 (the '362 patent)	March 19, 2040*
12,384,743 (the '743 patent)	November 1, 2038
12,390,419 (the '419 patent)	September 5, 2037

* 75 mg strength only

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 Solriamfetol Tablets, 75 mg and 150 mg, under this ANDA. You have notified the Agency that Hikma Pharmaceuticals USA Inc. (Hikma) 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 Hikma for infringement of the '715, '151, 12'609, '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. Hikma Pharmaceuticals USA Inc., et al., Civil Action No. 23-20354]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Hikma was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Solriamfetol Tablets 75 mg and 150 mg. Therefore, with this approval, Hikma is eligible for 180 days of shared generic drug exclusivity for Solriamfetol Tablets 75 mg and 150 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). 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).

We note that Hikma was granted a Competitive Generic Therapy (CGT) designation for Solriamfetol Tablets 75 mg and 150 mg. However, Hikma is not a "first approved applicant" for such competitive generic therapies, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because these drug products are eligible for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. See section 505(j)(5)(B)(v)(III)(bb)(BB) of the FD&C Act. Therefore, these drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) 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.

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 at 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 Kendra S. Stewart, R.Ph., Pharm.D.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul
Levine

Digitally signed by Paul Levine
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