ANDA 218211

ANDA APPROVAL

Syneos Health, LLC
U.S. Agent for Gland Pharma Limited
1030 Sync Street
Morrisville, NC 27560
Attention: Theresa Broomall
Publishing Consultant

Dear Theresa Broomall:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 5, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ephedrine Sulfate Injection USP, 50 mg/10 mL (5 mg/mL) Single-Dose Vials.

Reference is also made to the tentative approval letter issued by this office on September 20, 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. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Ephedrine Sulfate Injection USP, 50 mg/10 mL (5 mg/mL) Single-Dose Vials to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Emerphed Injection, 50 mg/10 mL (5 mg/mL), of Nexus Pharmaceuticals, LLC (Nexus) NDA - 213407.

The RLD upon which you have based your ANDA, Nexus's Emerphed Injection, 50 mg/10 mL (5 mg/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.S. Patent Number	Expiration Date
11,090,278 (the '278 patent)	May 16, 2040
11,241,400 (the '400 patent)	May 16, 2040
11,464,752 (the '752 patent)	May 16, 2040
11,478,436 (the '436 patent)	May 16, 2040

11,571,398 (the '398 patent) May 16, 2040

Your ANDA contains paragraph IV certifications to each of the patents[1], 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 Ephedrine Sulfate Injection USP, 50 mg/10 mL (5 mg/mL) Single-Dose Vials, under this ANDA. You have notified the Agency that Gland Pharma Limited (Gland) 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 Gland for infringement of the '278, '400, and '436 patents in the United States District Court for the District of New Jersey [Nexus Pharmaceuticals, Inc. v. Gland Pharma Limited, Civil Action No. 23-02032]. You have also notified the Agency that this case was dismissed.

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 as 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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The Agency notes that the '398 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

Catherine Poole

Digitally signed by Catherine Poole
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