ANDA 216159

ANDA APPROVAL

Hikma Pharmaceuticals USA Inc.
2 Esterbrook Lane
Cherry Hill, NJ 08003
Attention: Venkata Sai Tankashala
Associate Director, Regulatory Affairs

Dear Venkata Sai Tankashala:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on September 29, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL) Single-Dose Bags.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on July 26, 2022, 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 Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL) Single-Dose Bags to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL), of InfoRLife SA (InfoRLife).

The RLD upon which you have based your ANDA, InfoRLife's Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1mg/mL) and 100 mg/100 mL (1 mg/mL), is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
10,966,990 (the '990 patent)	June 20, 2038

Your ANDA contains a paragraph IV certification to the '990 patent, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL) Single-Dose Bags, under this ANDA. You have notified the Agency that Hikma Pharmaceuticals USA Inc. (Hikma Pharmaceuticals) 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 Pharmaceuticals for infringement of the '990 patent in the United States District Court for the District of Delaware [InfoRLife SA and WG Critical Care, LLC v. Hikma Pharmaceuticals USA Inc., Civil Action No. 21-01740 consolidated]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Hikma Pharmaceuticals was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL) Single-Dose Bags. Therefore, with this approval, Hikma Pharmaceuticals is eligible for 180 days of generic drug exclusivity for Midazolam in 0.9% Sodium Chloride Injection, 50 mg/50 mL (1 mg/mL) and 100 mg/100 mL (1 mg/mL) Single-Dose Bags. 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, will begin to run from the date of the commercial marketing 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).

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, 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

Catherine Poole

Digitally signed by Catherine Poole
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