NDA 019101/S-072

SUPPLEMENT APPROVAL

Hikma Pharmaceuticals USA Inc.
2 Esterbrook Lane
Cherry Hill, NJ 08003

Attention: Karen Deuter
Manager, Regulatory Affairs

Dear Karen Deuter:

Please refer to your supplemental new drug application (sNDA) dated and received on April 1, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fentanyl citrate injection.

This Prior Approval sNDA provides for changes to the immediate vial label for Fentanyl Citrate injection, 1 mL and 2 mL vials, specifically to remove the extended perforated label on the immediate vial labels which would delay administration of the drug, especially in the critical care setting.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon vial labeling.

CARTON AND CONTAINER LABELING

Submit final printed carton and container (vial) labeling that are identical to the enclosed vial labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 019101/S-072.** Approval of this submission by FDA is not required before the labeling is used.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR

314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact me via email at Jane.Mun@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Leah Crisafi, MD, FASA
Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LEAH H CRISAFI
09/25/2025 02:08:59 PM