NDA 019101/S-065

SUPPLEMENT APPROVAL

Hikma Pharmaceuticals USA Inc
Attention: Venkat Pericharla
Regulatory Affairs Manager
2 Esterbrook Lane
Cherry Hill, NJ 08003

Dear Venkat Pericharla:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 28, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fentanyl citrate injection.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

1. Removing the reference to mg (e.g., 0.05 mg/mL) from the strength statement of the carton labeling for currently marketed fentanyl products supplied in glass vials and ampules.
2. Removing the reference to mg (i.e., 0.05 mg) in the equivalency statement on the side panel of the carton labeling for currently marketed fentanyl products supplied in glass vials and ampules.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

We acknowledge your June 28, 2023, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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