NDA 018565/S-029

SUPPLEMENT APPROVAL

Hikma Pharmaceuticals USA Inc
Attention: Venkat Pericharla
Regulatory Affairs Manager
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Venkat Pericharla:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 9, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Duramorph (morphine sulfate injection) and Infumorph (morphine sulfate injection).

This "Changes Being Effected" supplemental new drug application provides for change in the filter statement of carton label from "Filter prior to use. 5µ filter enclosed." to "Filter prior to use through a 5µ (or smaller) microfilter" for Infumorph® (Preservative Free Morphine Sulfate Injection, USP).

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 October 20, 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:
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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