NDAs 005939/S-012, 011525/S-031, 012015/S-036, 016619/S-045, 019353/S-024 & 208609/S-006

SUPPLEMENT APPROVAL

Akorn Operating Company LLC
Attention: Jean Poulos
Head of Regulatory Affairs
5605 Centerpoint Court
Suite A
Gurnee, IL 60031

Dear Ms. Poulos:

Please refer to your Supplemental New Drug Application (sNDA) dated October 23, 2019, received October 23, 2019, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA/005939/S-012	BAL (dimercaprol injection)	October 23, 2019	October 23, 2019
NDA-011525/S-031	IC-Green (indocyanine green for Injection USP), 25 mg/vial	October 23, 2019	October 23, 2019
NDA 012015/S-036	Cogentin ® (benztropine mesylate injection), 1 mg/mL	October 23, 2019	October 23, 2019
NDA 016619/S-045	Fentanyl Citrate Injection, 50 mcg/mL	October 23, 2019	October 23, 2019
NDA 019353/S-024	Alfenta ® (alfentanil HCl Injection), 500 mcg/mL	October 23, 2019	October 23, 2019
NDA 208609/S-006	Ephedrine Sulfate Injection, 50 mg/mL	October 23, 2019	October 23, 2019

We also refer to our approval letter dated February 3, 2023, which contained the following error: typographical comments listed in the signature page.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 3, 2023, the date of the original approval letter.

We acknowledge receipt of your amendment dated August 6, 2022, which constituted a complete response to our April 10, 2020, action letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for (b) (4) (b) (4) and the addition of (b) (4)

APPROVAL

We have completed our review of these supplemental applications, as amended. These supplements are approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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