NDA 050592/S-051

APPROVAL LETTER

Sandoz Inc.
Attention: Gregory Seitz
Head US Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Gregory Seitz:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 30, 2024, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tobradex (tobramycin and dexamethasone ophthalmic suspension).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a (b) (4) on the secondary packaging component (carton) and removal of the (b) (4) (b) (4).

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 LABELS

Submit final printed carton labels that are identical to enclosed carton labels and carton labels submitted on December 26, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 050592/S-051.**" Approval of this submission by FDA is not required before the labeling is used.

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, please contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at shazma.aftab@fda.hhs.gov or (301) 796 - 3138.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Supervisor
Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton Labeling

David Lewis

Digitally signed by David Lewis
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