NDA 50592/S-044
NDA 50592/S-046

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Nancy A. Price
Global Program Regulatory Director, Life Cycle Management
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Price:

Please refer to your supplemental new drug applications (sNDA) dated May 14, 2018, and May 20, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TOBRADEX (tobramycin and dexamethasone ophthalmic suspension) 0.3%/0.1%. We acknowledge receipt of your amendment dated February 24, 2021, which constituted a complete response to our March 12, 2020, action letters. These Prior Approval supplemental new drug applications provide for the addition of adverse reactions reported with dexamethasone use, and the addition of adverse reactions reported with the use of systemic aminoglycosides, in the Adverse Reactions section of the Prescribing Information.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

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 Derek Alberding, Regulatory Health Project Manager, at (240) 402-0963.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

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/

WILEY A CHAMBERS
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