

NDA 19845/S-030

## SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation  
Attention: Suzanne Brabant  
Global Program Regulatory Director  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Ms. Brabant:

Please refer to your supplemental new drug application (sNDA) dated and received May 31, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BETOPTIC S (betaxolol hydrochloride ophthalmic suspension), 0.25%. We acknowledge receipt of your amendment dated November 16, 2020, which constituted a complete response to our February 4, 2020, action letter. This Prior Approval sNDA provides for revisions to the Prescribing Information to comply with the content and format requirements of the Pregnancy and Lactation Labeling Rule (PLLR).

### **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](http://www.fda.gov).<sup>1</sup> 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*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

**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, Clinical Analyst, 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

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**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.**  
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/s/  
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