



NDA 20816/S019

**SUPPLEMENT APPROVAL**

Alcon Pharmaceuticals, Inc  
Attention: Suzanne Cadden  
Head of Regulatory Affairs  
6201 South Freeway  
Mail Code TA6-1  
Fort Worth, TX 76134-2099

Dear Ms. Cadden:

Please refer to your Supplemental New Drug Application (sNDA) dated July 21, 2015, received July 22, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AZOPT (brinzolamide ophthalmic suspension), 1%. We also refer to your October 30, 2015, submission containing updated labeling information.

This "Prior Approval" supplemental new drug application provides for the following revisions to the package insert (additions are underlined, deletions are in ~~striketrough~~):

1. In the **FULL PRESCRIBING INFORMATION, 2 DOSAGE AND ADMINISTRATION**, a second sentence is reintroduced to the labeling, as it was omitted in previous labeling in error.

**2 DOSAGE AND ADMINISTRATION**

The recommended dose is one drop of AZOPT (brinzolamide ophthalmic suspension) 1% in the affected eye(s) three times daily. AZOPT (brinzolamide ophthalmic suspension) 1% may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart.

2. In the **13 NONCLINICAL TOXICOLOGY/13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**, the beginning of the paragraph is revised as follows:

Carcinogenicity data on brinzolamide are not available. Brinzolamide caused urinary bladder tumors in female mice at oral doses of 10 mg/kg/day and in male rats at oral doses of 8 mg/kg/day in 2 year studies. Brinzolamide was not carcinogenic in male mice or female rats dosed orally for up to 2 years. The carcinogenicity appears secondary to kidney and urinary bladder toxicity. These levels of exposure cannot be achieved with topical ophthalmic dosing in humans

3. Numerous editorial changes

## **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 text, which is identical to the package insert submitted on October 30, 2015.

## **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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling for the package insert, 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 titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **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 Judit Milstein, Regulatory Project Manager, at (301) 796-0763.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, MD  
Deputy Director  
Division of Transplant and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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WILEY A CHAMBERS  
11/10/2015

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