Clinical Review of NDA 19-992
Labeling Supplement

NDA 19-992 /S-026
SDN-216

Submission Date: 2/16/16
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Review Date: 3/8/16

Applicant:

Alcon, Inc.
P.O. Box 62
Bosch 69
CH-6331 Hunenberg
Switzerland

Authorized U.S. Agent
Alcon Research, Ltd.
6201 S. Freeway
Fort Worth, Texas

Applicant's Representative:

Phillip Reveal, MS
Regulatory Affairs Global Franchise Pharmaceuticals
Ophthalmology
Novartis Pharmaceuticals Corporation
6201 South Freeway
Fort Worth, TX 76134-2099, USA

Drug: CILOXAN (ciprofloxacin ophthalmic solution) 0.3%

Pharmacologic Category: Topical anti-microbial

Submitted:

Reference is made to the original NDA for CILOXAN (ciprofloxacin ophthalmic solution) 0.3% approved on December 31, 1990. Reference is also made to the Agency's letter of June 13, 2016, requesting that Alcon revise the established name of the drug product in all labeling to be consistent with the current USP Monograph for ciprofloxacin ophthalmic solution. In accordance with the Agency's request, Alcon has submitted a prior approval labeling supplement with revised draft labeling.

The labeling submitted on 2/16/16 also contains Agency requested revisions to the Clinical Studies and Pediatric Use Sections. On October 22, 1999, a Written Request (with subsequent amendments on August 3, 2001, and September 6, 2002) was issued to conduct a clinical study to provide pediatric information on ciprofloxacin. The sponsor conducted a 9-day multicenter, randomized, double-masked, parallel group study that compared Ciloxan 0.3% dosed three times a day to moxifloxacin ophthalmic solution 0.5% dosed three times a day in neonates from birth to 31 days of age. The Clinical Studies and Pediatric Use Sections have been updated.

Following is the package insert submitted on 10/7/16. Applicant additions to the approved package insert are noted by underline and deletions are noted by .

5 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immeidately following this page

Reviewer's Comments:

The applicant has made appropriate revisions to the established name consistent with current USP Monograph for ciprofloxacin ophthalmic solution. Acceptable.

The applicant has accepted the revisions to the Clinical Studies and Pediatric Use Sections *as required by the Best Pharmaceuticals for Children Act (BPCA). The minor editorial revisions to these Sections as proposed by the applicant are acceptable.*

Minor administrative revisions throughout the label are acceptable.

Recommendation:

This supplemental application which provides for revision to the established name consistent with current USP Monograph for ciprofloxacin ophthalmic solution is recommended for approval. The additional revisions to the Clinical Studies and Pediatric Use Section and the minor editorial revisions to the labeling are acceptable. The revised carton and container labeling (see Medical Officer's review in DARRTS dated 11/4/2016) are acceptable.

William M. Boyd, M.D.
Clinical Team Leader

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/s/

WILLIAM M BOYD
03/09/2017

WILEY A CHAMBERS
03/10/2017