Clinical Review of NDA 21-598
Labeling Supplement

NDA 21-598 /S-022
SDN-460

Submission Date: 2/16/17
Receipt Date: 2/16/17
Review Date: 2/27/17

Applicant:
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Applicant's Representative:
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Drug:
VIGAMOX (moxifloxacin ophthalmic solution) 0.5%

Pharmacologic Category:
Anti-infective (fluoroquinolone)

Submitted:

Reference is made to the original NDA for VIGAMOX approved on April 15, 2003. Reference is also made to the Agency's letter of May 31, 2016, requesting that Alcon revise the established name of the drug product in all labeling to be consistent with the current USP Monograph for moxifloxacin 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 Sections 8.4 and 12. On June 26, 2000, a Written Request (with a subsequent amendment on September 6, 2002) was issued to conduct a clinical study to provide pediatric information on moxifloxacin. The sponsor conducted 9-day multi-center, randomized, double-masked, parallel-group clinical trial (Study C-01-34) that compared VIGAMOX (moxifloxacin ophthalmic solution, 0.5% versus Ciloxan (ciprofloxacin ophthalmic solution) 0.3%; each were dosed three times a day for four days in neonates from birth to 31 days of age. (b) (4) As required by the Best Pharmaceuticals for Children Act (BPCA) (21 U.S.C. 355a), data submitted in response to a Written Request under the BPCA and assessments submitted in response to a PREA study requirement must be described in labeling whether findings are positive, negative, or inconclusive (sections 505A(j) and 505B(g)(2) of the FD&C Act). Sections 8.4 and 12 have been updated.

Following is the package insert submitted on 9/30/16. Additions to the approved package insert are noted by underline and deletions are noted by .

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

(b) (4)

(b) (4)

[redacted]

Reviewer's Comments:

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

The applicant corrected the format of a cross-reference in Section 12.1. Acceptable.

The applicant has accepted the revisions to Section 8.4 and 12 as required by the Best Pharmaceuticals for Children Act (BPCA). The minor editorial revisions to these Sections as proposed by the applicant are acceptable.

In Section 17, the applicant has added subheadings and revised patient counseling information into directive language. 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 moxifloxacin ophthalmic solution is recommended for approval. The additional revisions to Sections 8.4 and 12 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
02/28/2017

WILEY A CHAMBERS
02/28/2017