

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22428Orig1s000

OTHER ACTION LETTER(s)



NDA 22-428

COMPLETE RESPONSE

Alcon Research Ltd.
Attention: Ms. Karen Lankow
Associate Director, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Ms. Lankow:

Please refer to your new drug application (NDA) dated December 12, 2008, received December 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for moxifloxacin hydrochloride ophthalmic solution 0.5% as base.

We acknowledge receipt of your amendments dated February 10, 25 and 26, April 9, May 4 and 29, June 11, July 2 and August 25, 2009.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described below our reasons for this action and, where possible, our recommendations to address these issues.

Per 21 CFR 314.125(5), there is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in 314.126, that the drug product will have the effect it purports or is represented to have under the conditions or use prescribed, recommended, or suggested in its proposed labeling. Specifically, there is not substantial evidence demonstrating that moxifloxacin hydrochloride ophthalmic solution 0.5% as base when dosed two times a day for three days was superior to a control in the treatment of bacterial conjunctivitis in patients one month of age and older.

At least one additional adequate and well-controlled clinical study will be required to demonstrate the efficacy of moxifloxacin hydrochloride ophthalmic solution 0.5% as base for the treatment of bacterial conjunctivitis.

We will continue to work with you on your future development plans for moxifloxacin hydrochloride ophthalmic solution including labeling and encourage you to discuss any future protocols for clinical studies with the Division.

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A

resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's *Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants*, May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Lori Gorski, Regulatory Project Manager, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22428	ORIG-1	ALCON PHARMACEUTICA LS LTD	MOXIFLOXACIN ALTERNATIVE FORMULATION OP

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILEY A CHAMBERS
10/07/2009