

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22428Orig1s000

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

EXCLUSIVITY SUMMARY

NDA # 22-428

SUPPL #

HFD # 520

Trade Name Moxeza

Generic Name moxifloxacin hydrochloride ophthalmic solution 0.5% as base

Applicant Name Alcon Research , Ltd

Approval Date, If Known November 19, 2010

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(1)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

Yes

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#	21-598	Vigamox (moxifloxacin hydrochloride ophthalmic solution) 0.5% as base
NDA#	21-085	Avelox (moxifloxacin hydrochloride) tablet
NDA#	21-277	Avelox (moxifloxacin hydrochloride) IV
NDA#	21-334	Avelox (moxifloxacin hydrochloride) 400 mg tablet

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)
IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Study C-04-38
Study C-04-40
Study C-07-40

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

- a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1	Study C-04-38	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
Investigation #2	Study C-04-70	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
Investigation #2	Study C-07-40	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

- b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1	Study C-04-38	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
Investigation #2	Study C-04-70	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>

Investigation #2 Study C-07-40 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Study C-04-38
Study C-04-40
Study C-07-40

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 Study C-04-38 !
IND # 59,944 YES ! NO
! Explain:

Investigation #2 Study C-04-40 !
IND # 59,944 YES ! NO
! Explain:

Investigation #3 Study C-0740 !
IND # 59,944 YES ! NO
! Explain:

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

/s/

LORI M GORSKI
11/19/2010
exclusivity summary

WILEY A CHAMBERS
11/19/2010



NDA 022428

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Alcon Pharmaceuticals Ltd.
c/o Alcon Research Ltd.
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

ATTENTION: Karen Lankow
Associate Director, Regulatory Affairs

Dear Ms. Lankow:

Please refer to your New Drug Application (NDA) resubmission dated May 20, 2010, received May 21, 2010, 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 November 16, 2010, correspondence, on November 17, 2010, notifying us that you are withdrawing your request for a review of the proposed proprietary name, (b) (4). This proposed proprietary name request is considered withdrawn as of November 17, 2010.

We also acknowledge that you have proposed an alternate proprietary name, Moxeza, in your submission dated November 16, 2010.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Brantley Dorch, Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh.
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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

/s/

DENISE P TOYER on behalf of CAROL A HOLQUIST
11/19/2010



NDA 022428

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Alcon Pharmaceuticals Ltd.
c/o Alcon Research Ltd
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

ATTENTION: Karen Lankow
Associate Director, Regulatory Affairs

Dear Ms Lankow:

Please refer to your New Drug Application (NDA) resubmission dated May 20, 2010, received May 21, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moxifloxacin Hydrochloride Ophthalmic Solution, 0.5% as base.

We also refer to your November 16, 2010, correspondence, received November 17, 2010, requesting review of your proposed proprietary name, Moxeza. We have completed our review of the proposed proprietary name, Moxeza, and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your November 16, 2010, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Denise P. Toyer, PharmD
Deputy Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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

/s/

DENISE P TOYER
11/19/2010

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION ¹		
NDA # 22-428 BLA #	NDA Supplement # BLA STN #	If NDA, Efficacy Supplement Type:
Proprietary Name: Moxeza Established/Proper Name: moxifloxacin hydrochloride ophthalmic solution Dosage Form: ophthalmic solution		Applicant: Alcon Research Ltd Agent for Applicant (if applicable):
RPM: Lori Marie Gorski		Division: Division of Anti-Infective and Ophthalmology Products
<p><u>NDA</u>s:</p> <p>NDA Application Type: <input checked="" type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)</p>		<p><u>505(b)(2) Original NDAs and 505(b)(2) NDA supplements:</u></p> <p>Listed drug(s) relied upon for approval (include NDA #(s) and drug name(s)):</p> <p>Provide a brief explanation of how this product is different from the listed drug.</p> <p>If no listed drug, explain.</p> <p><input type="checkbox"/> This application relies on literature.</p> <p><input type="checkbox"/> This application relies on a final OTC monograph.</p> <p><input type="checkbox"/> Other (explain)</p> <p><u>Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.</u></p> <p><u>On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.</u></p> <p><input type="checkbox"/> No changes <input type="checkbox"/> Updated Date of check:</p> <p>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</p>
❖ Actions		
<ul style="list-style-type: none"> • Proposed action • User Fee Goal Date is <u>November 21, 2010</u> 		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR
<ul style="list-style-type: none"> • Previous actions (<i>specify type and date for each action taken</i>) 		<input type="checkbox"/> None October 7, 2009 Complete Response

¹ The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

<p>❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____</p>	<input type="checkbox"/> Received
<p>❖ Application Characteristics²</p>	
<p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority Chemical classification (new NDAs only):</p> <p><input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch <input type="checkbox"/> Orphan drug designation <input type="checkbox"/> Direct-to-OTC</p> <p>NDAs: Subpart H BLAs: Subpart E <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <input type="checkbox"/> Accelerated approval (21 CFR 601.41) <input type="checkbox"/> Restricted distribution (21 CFR 314.520) <input type="checkbox"/> Restricted distribution (21 CFR 601.42) Subpart I Subpart H <input type="checkbox"/> Approval based on animal studies <input type="checkbox"/> Approval based on animal studies</p> <p><input type="checkbox"/> Submitted in response to a PMR REMS: <input type="checkbox"/> MedGuide <input type="checkbox"/> Submitted in response to a PMC <input type="checkbox"/> Communication Plan <input type="checkbox"/> Submitted in response to a Pediatric Written Request <input type="checkbox"/> ETASU <input type="checkbox"/> REMS not required</p> <p>Comments:</p>	
<p>❖ BLAs only: Ensure <i>RMS-BLA Product Information Sheet for TBP</i> and <i>RMS-BLA Facility Information Sheet for TBP</i> have been completed and forwarded to OPI/OBI/DRM (Vicky Carter)</p>	<input type="checkbox"/> Yes, dates
<p>❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>❖ Public communications (<i>approvals only</i>)</p>	
<ul style="list-style-type: none"> Office of Executive Programs (OEP) liaison has been notified of action 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> Press Office notified of action (by OEP) 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> Indicate what types (if any) of information dissemination are anticipated 	<input checked="" type="checkbox"/> None <input type="checkbox"/> HHS Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other

² Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> Is approval of this application blocked by any type of exclusivity? 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> NDA and BLAs: Is there existing orphan drug exclusivity for the “same” drug or biologic for the proposed indication(s)? <i>Refer to 21 CFR 316.3(b)(13) for the definition of “same drug” for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions. 	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent. 	21 CFR 314.50(i)(1)(i)(A) <input type="checkbox"/> Verified 21 CFR 314.50(i)(1) <input type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> [505(b)(2) applications] If the application includes a paragraph III certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval). 	<input type="checkbox"/> No paragraph III certification Date patent will expire
<ul style="list-style-type: none"> [505(b)(2) applications] For each paragraph IV certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). <i>(If the application does not include any paragraph IV certifications, mark “N/A” and skip to the next section below (Summary Reviews)).</i> 	<input type="checkbox"/> N/A (no paragraph IV certification) <input type="checkbox"/> Verified

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

Answer the following questions for **each** paragraph IV certification:

- (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification?

Yes No

(Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e)).

If "Yes," skip to question (4) below. If "No," continue with question (2).

- (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.

If "No," continue with question (3).

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)).

If "No," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.

- (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).

If "No," continue with question (5).

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period).</p> <p><i>If "No," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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CONTENTS OF ACTION PACKAGE

❖ Copy of this Action Package Checklist ³	x
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (<i>approvals only</i>)	<input checked="" type="checkbox"/> Included
Documentation of consent/non-consent by officers/employees	<input checked="" type="checkbox"/> Included
Action Letters	
❖ Copies of all action letters (<i>including approval letter with final labeling</i>)	Action(s) and date(s) CR October 7, 2009
Labeling	
❖ Package Insert (<i>write submission/communication date at upper right of first page of PI</i>)	
<ul style="list-style-type: none"> • Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. 	November 18, 2010
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	December 12, 2008
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	NA

³ Fill in blanks with dates of reviews, letters, etc.
Version: 8/25/10

<ul style="list-style-type: none"> ❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling (<i>write submission/communication date at upper right of first page of each piece</i>) 	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input type="checkbox"/> Device Labeling <input checked="" type="checkbox"/> None
<ul style="list-style-type: none"> • Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. 	NA
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	NA
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	NA
<ul style="list-style-type: none"> ❖ Labels (full color carton and immediate-container labels) (<i>write submission/communication date on upper right of first page of each submission</i>) 	
<ul style="list-style-type: none"> • Most-recent draft labeling 	November 18, 2010
<ul style="list-style-type: none"> ❖ Proprietary Name <ul style="list-style-type: none"> • Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>) • Review(s) (<i>indicate date(s)</i>) 	December 8, 2009 denied (b) (4) September 2, 2010 denied (b) (4) August 27, 2009 (b) (4) November 2, 2010 (b) (4) November 19, 2010 Moxez (b) (4)
<ul style="list-style-type: none"> ❖ Labeling reviews (<i>indicate dates of reviews and meetings</i>) 	<input type="checkbox"/> RPM <input type="checkbox"/> DMEPA <input type="checkbox"/> DRISK <input checked="" type="checkbox"/> DDMAC October 4, 2010 <input type="checkbox"/> CSS <input type="checkbox"/> Other reviews
Administrative / Regulatory Documents	
<ul style="list-style-type: none"> ❖ Administrative Reviews (<i>e.g., RPM Filing Review⁴/Memo of Filing Meeting</i>) (<i>indicate date of each review</i>) 	RPM filing review 9/28/09
<ul style="list-style-type: none"> ❖ All NDA (b)(2) Actions: Date each action cleared by (b)(2) Clearance Cmte 	<input checked="" type="checkbox"/> Not a (b)(2)
<ul style="list-style-type: none"> ❖ NDA (b)(2) Approvals Only: 505(b)(2) Assessment (<i>indicate date</i>) 	<input checked="" type="checkbox"/> Not a (b)(2)
<ul style="list-style-type: none"> ❖ NDAs only: Exclusivity Summary (<i>signed by Division Director</i>) 	<input type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm 	
<ul style="list-style-type: none"> • Applicant is on the AIP 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> • This application is on the AIP <ul style="list-style-type: none"> ○ If yes, Center Director's Exception for Review memo (<i>indicate date</i>) ○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>) 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not an AP action
<ul style="list-style-type: none"> ❖ Pediatrics (<i>approvals only</i>) <ul style="list-style-type: none"> • Date reviewed by PeRC <u>November 17, 2010</u> If PeRC review not necessary, explain: _____ • Pediatric Page/Record (<i>approvals only, must be reviewed by PERC before finalized</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent (<i>include certification</i>) 	<input checked="" type="checkbox"/> Verified, statement is acceptable

⁴ Filing reviews for scientific disciplines should be filed behind the respective discipline tab.
Version: 8/25/10

❖ Outgoing communications (<i>letters (except action letters), emails, faxes, telecons</i>)	in package
❖ Internal memoranda, telecons, etc.	In Package
❖ Minutes of Meetings	
• Regulatory Briefing (<i>indicate date of mtg</i>)	<input checked="" type="checkbox"/> No mtg
• If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>)	<input checked="" type="checkbox"/> N/A or no mtg
• Pre-NDA/BLA meeting (<i>indicate date of mtg</i>)	<input type="checkbox"/> No mtg July 28, 2008
• EOP2 meeting (<i>indicate date of mtg</i>)	<input checked="" type="checkbox"/> No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) (<i>indicate dates of mtgs</i>)	NA
❖ Advisory Committee Meeting(s)	<input checked="" type="checkbox"/> No AC meeting
• Date(s) of Meeting(s)	NA
• 48-hour alert or minutes, if available (<i>do not include transcript</i>)	NA
Decisional and Summary Memos	
❖ Office Director Decisional Memo (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Division Director Summary Review (<i>indicate date for each review</i>)	<input type="checkbox"/> None October 7, 2009 November 19, 2010
Cross-Discipline Team Leader Review (<i>indicate date for each review</i>)	<input type="checkbox"/> None October 7, 2010 November 19, 2010
PMR/PMC Development Templates (<i>indicate total number</i>)	<input checked="" type="checkbox"/> None
Clinical Information⁵	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) (<i>indicate date for each review</i>)	October 7, 2009 November 19, 2010
• Clinical review(s) (<i>indicate date for each review</i>)	August 12, 2009 November 19, 2010
• Social scientist review(s) (if OTC drug) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not (<i>indicate date of review/memo</i>)	in clinical review
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers (<i>indicate date of each review</i>)	<input checked="" type="checkbox"/> None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation (<i>indicate date of each review</i>)	<input checked="" type="checkbox"/> Not applicable
❖ Risk Management <ul style="list-style-type: none"> • REMS Documents and Supporting Statement (<i>indicate date(s) of submission(s)</i>) • REMS Memo(s) and letter(s) (<i>indicate date(s)</i>) • Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>) 	<input checked="" type="checkbox"/> None
❖ DSI Clinical Inspection Review Summary(ies) (<i>include copies of DSI letters to investigators</i>)	<input type="checkbox"/> None requested July 8, 2009 October 6, 2010

⁵ Filing reviews should be filed with the discipline reviews.
Version: 8/25/10

Clinical Microbiology <input type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Clinical Microbiology Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None August 24, 2009 <input type="checkbox"/> August 24, 2010
Biostatistics <input type="checkbox"/> None	
❖ Statistical Division Director Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Statistical Team Leader Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Statistical Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None September 16, 2009 <input type="checkbox"/> October 1, 2010
Clinical Pharmacology <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
Clinical Pharmacology review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None July 15, 2009 <input type="checkbox"/> August 20, 2010
❖ DSI Clinical Pharmacology Inspection Review Summary (<i>include copies of DSI letters</i>)	<input checked="" type="checkbox"/> None
Nonclinical <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Supervisory Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Pharm/tox review(s), including referenced IND reviews (<i>indicate date for each review</i>)	<input type="checkbox"/> None July 14, 2010
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary (<i>include copies of DSI letters</i>)	<input checked="" type="checkbox"/> None requested
Product Quality <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Branch Chief/Team Leader Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Product quality review(s) including ONDQA biopharmaceutics reviews (<i>indicate date for each review</i>)	<input type="checkbox"/> None August 26, 2009 <input type="checkbox"/> October 5, 2010
❖ Microbiology Reviews	<input type="checkbox"/> Not needed September 29, 2009 July 19, 2010
<input checked="" type="checkbox"/> NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) (<i>indicate date of each review</i>)	
<input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) (<i>indicate date of each review</i>)	NA
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer (<i>indicate date of each review</i>)	<input checked="" type="checkbox"/> None

❖ Environmental Assessment (check one) (original and supplemental applications)	
<input type="checkbox"/> Categorical Exclusion (<i>indicate review date</i>)(<i>all original applications and all efficacy supplements that could increase the patient population</i>)	Claims exclusion CMC review pg 43
<input type="checkbox"/> Review & FONSI (<i>indicate date of review</i>)	NA
<input type="checkbox"/> Review & Environmental Impact Statement (<i>indicate date of each review</i>)	No additional impact
❖ Facilities Review/Inspection	
<input type="checkbox"/> NDAs: Facilities inspections (include EER printout) (<i>date completed must be within 2 years of action date</i>) (<i>only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites⁶</i>)	Date completed: September 30, 2010 all dates acceptable in EES <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation <input type="checkbox"/> Not applicable
<input type="checkbox"/> BLAs: TB-EER (<i>date of most recent TB-EER must be within 30 days of action date</i>) (<i>original and supplemental BLAs</i>)	Date completed: NA <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
❖ NDAs: Methods Validation (<i>check box only, do not include documents</i>)	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input type="checkbox"/> Not needed (per review)

⁶ I.e., a new facility or a change in the facility, or a change in the manufacturing process in a way that impacts the Quality Management Systems of the facility.

Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

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/s/

LORI M GORSKI
11/19/2010
action package checklist



NDA 022428

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Alcon Research Ltd.
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

ATTENTION: Karen Lankow
Associate Director, Regulatory Affairs

Dear Ms. Lankow:

Please refer to your New Drug Application (NDA) resubmission dated May 20, 2010, received May 21, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moxifloxacin Hydrochloride Ophthalmic Solution, 0.5%.

We acknowledge receipt of your October 15, 2010, correspondence, on October 18, 2010, notifying us that you are withdrawing your request for a review of the proposed proprietary name, (b) (4). This proposed proprietary name request is considered withdrawn as of October 18, 2010.

We also acknowledge that you have proposed an alternate proprietary name, (b) (4) in your submission dated October 15, 2010.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Brantley Dorch, Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

BRANTLEY H DORCH
10/29/2010

CAROL A HOLQUIST
11/02/2010

MEMORANDUM OF MEETING MINUTES

Meeting Type: FDA-Initiated Teleconference Meeting
Time: October 13, 2010; 1:30 PM – 2:00 PM EST
Meeting Location: WO Bldg 22, RM 3201
Application Type and Number: NDA 22428
Product Name: Moxifloxacin Ophthalmic Solution 0.5%
Indication: Treatment of bacterial conjunctivitis
Sponsor/Applicant Name: Alcon Research, Ltd.

Meeting Chair: Kristina Toliver, Pharm D
Meeting Recorder: Brantley Dorch, Pharm D

FDA ATTENDEES

Kristina Toliver, Pharm D, Team Leader	DMEPA
Lori Cantin, Pharm D, Safety Evaluator	DMEPA
Lori Gorski, Project Manager	DAIOP
Sean Bradley R.Ph, Team Leader	Project Management Staff
Brantley Dorch, Pharm D	Safety Regulatory Project Manager

SPONSOR PARTICIPANTS

Alex Long, VP, Global Pharmaceutical Marketing	Alcon Research, Ltd.
Paul Hallen, Director of Global Marketing	Alcon Research, Ltd.
Jim Sluck, US Marketing Director, Acute Diseases	Alcon Research, Ltd.
John Caron, Global Product Marketing Manager	Alcon Research, Ltd.
Michael Pflieger, VP, Regulatory Affairs	Alcon Research, Ltd.
Angela Kothe, Regulatory Affairs	Alcon Research, Ltd.
Karen Lankow, Regulatory Affairs	Alcon Research, Ltd.

(b) (4)

BACKGROUND:

NDA 22428 is a Class 2 Resubmission currently under review in the Division of Anti-Infectives and Ophthalmology Products. The OND PDUFA date for this NDA is November 21, 2010. On June 8, 2010, the Applicant submitted a request for proprietary name review for proposed name, (b) (4)

The Division of Medication Error Prevention and Analysis (DMEPA), evaluated the proposed name, (b) (4) and found the name unacceptable due (b) (4)

On September 30, 2010, Alcon submitted a new request for proprietary name review proposing the name, (b) (4) DMEPA's preliminary evaluation indicates that there is still a risk of confusion and medication errors between (b) (4) and Vigamox, (b) (4)

MEETING OBJECTIVES:

- Discuss DMEPA's objection to the proposed proprietary name, (b) (4)
- Discuss the Applicant's options for seeking approval of a proprietary name for Moxifloxacin Ophthalmic Solution, 0.5%.

DISCUSSION POINTS:

- DMEPA indicated that their preliminary evaluation of the proposed name, (b) (4) introduces similar issues that were identified with (b) (4) and Vigamox due to (b) (4). Additionally, DMEPA has concerns with respect to computer order entry and computer selection errors due to the (b) (4)

(b) (4)

- Similar product characteristics
 - Same active ingredient (Moxifloxacin)
 - Same strength (0.5%)
 - Route of Administration (topical ophthalmic)
 - Dose (1 drop)
 - Duration of therapy (7 days)

(b) (4)

- DMEPA explained that name confusion has been documented in the post-marketing setting with family trade names tha (b) (4)
- DMEPA indicated that increasing letter quantity does reduce the risk, but it does not address the computer order entry issue.
- (b) (4)
- The Applicant inquired about other approved names for ophthalmic products that are manufactured by the same company such as Zymar and Zymaxid or Acular and Acuvail.
- (b) (4)
- DMEPA informed the Applicant of their options which are
 - to wait for the full review to be completed in which case a subsequent denial letter will be issued or
 - after the denial letter is received, submit a rebuttal with data to address the discussed concerns and support the proposed name, (b) (4) or
 - withdraw the proposed name, (b) (4) and submit a new request for proprietary name review with multiple names.

ACTION ITEMS:

- The Applicant will withdraw the name, (b) (4) and submit three new names for review.

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/s/

BRANTLEY H DORCH
11/04/2010

REQUEST FOR DDMAC LABELING REVIEW CONSULTATION

****Please send immediately following the Filing/Planning meeting****

TO: **Wayne Amchin**
DDMAC Regulatory Project Manager

FROM: (Name/Title, Office/Division/Phone number of requestor)
Lori Gorski
Project Manager
Division of Anti-Infective & Ophthalmology Products
Phone 301-796-0722
E-mail lori.gorski@fda.hhs.gov

REQUEST DATE
September 22, 2010

IND NO.

NDA 22-428

TYPE OF DOCUMENTS
Original NDA

NAME OF DRUG
Moxifloxacin AF
(moxifloxacin hydrochloride
ophthalmic solution) 0.5%

PRIORITY CONSIDERATION

CLASSIFICATION OF DRUG

DESIRED COMPLETION DATE
(Generally 1 week before the wrap-up meeting)
One week from your receipt or
sooner

NAME OF FIRM:
Alcon

Labeling meeting is October 4, 2010 – please respond prior to
meeting

TYPE OF LABEL TO REVIEW

TYPE OF LABELING:
(Check all that apply)

PACKAGE INSERT (PI)

TYPE OF APPLICATION/SUBMISSION
 ORIGINAL NDA/BLA

REASON FOR LABELING CONSULT
 INITIAL PROPOSED LABELING

EDR link to submission:

This is a paper submission. The label is attached.

Please Note: There is no need to send labeling at this time. DDMAC reviews substantially complete labeling, which has already been marked up by the CDER Review Team. The DDMAC reviewer will contact you at a later date to obtain the substantially complete labeling for review.

COMMENTS/SPECIAL INSTRUCTIONS:

Attached is the Divisions revised label for moxifloxacin AF. The Divisions labeling meeting is October 4, 2010 at 9 AM. Please provide comments to Lori Gorski via email prior to the meeting. Thanks – Lori Gorski 796-0722

There is currently no proprietary name under review for this application. The most recently submitted name, (b) (4) was reviewed and denied by DMEPA. Alcon has not submitted a new name yet.

Labeling Meetings: We may have one more labeling meeting if needed, there is not currently one scheduled.

SIGNATURE OF REQUESTER
Lori Marie Gorski

SIGNATURE OF RECEIVER

METHOD OF DELIVERY (Check one)
 eMAIL HAND

7 pages of draft labeling has been withheld in full as B(4) CCI/TS immediately following this page

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/s/

LORI M GORSKI

09/23/2010

Please provide Lori Gorski with comments prior to the October 4, 2010 labeling meeting! thanks!

Gorski, Lori M

From: Gorski, Lori M
Sent: Friday, September 17, 2010 1:01 PM
To: 'Lankow,Karen,FORT WORTH,Regulatory Affairs'
Cc: 'Schafer,Norma,FORT WORTH,Regulatory Affairs'
Subject: NDA 22-428, request for clinical information

Hi Karen,

Regarding NDA 22-428, Moxifloxacin AF, the clinical reviewer is requesting the following information. Please respond with an official submission through the document control room. If you wouldn't mind, please also forward me a copy of your response via email at the time it is submitted.

Thanks for your quick response in this matter. Call me if you have any questions.

1. Table 2.7.3.3.2.2.-7 in Module 2, Volume 1, Section 2.7.3 (Summary of Clinical Efficacy) identifies the combined (Studies C-04-38, C-04-40, and C-07-40) eradication rate and clinical cure/clinical failure by organisms in patients treated with Moxifloxacin AF in the MBITT population. A similar table (clinical cure/clinical failure by organisms) for each individual study (Studies C-04-38, C-04-40, and C-07-40) should be provided. In addition, the tables should include the data of the control group for each study. If this information has already been submitted to the NDA, please provide the exact location.
2. Table 2.7.4.1.3.3.-4 in Module 2, Volume 1, Section 2.7.4 (Summary of Clinical Safety) gives the listing of patients less than 1 year old who were enrolled in Studies C-04-38, C-04-40, and C-07-40. For each of the patient listed, please include a column identifying whether the patient was a clinical cure or a clinical failure. If this information has already been submitted to the NDA, please provide the exact location.

Lori Gorski
Project Manager
Division of Anti-Infective & Ophthalmology Products
Phone 301-796-0722
Fax 301-796-9881
E-mail lori.gorski@fda.hhs.gov

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/s/

LORI M GORSKI
09/17/2010
request for clin info



NDA 022428

**PROPRIETARY NAME REQUEST
UNACCEPTABLE**

Alcon Pharmaceuticals Ltd.
c/o Alcon Research Ltd.
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

ATTENTION: Karen Lankow
Associate Director, Regulatory Affairs

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%.

We also refer to your June 8, 2010, correspondence, received June 9, 2010, requesting review of your proposed proprietary name, (b) (4). We have completed our review of the proposed proprietary name, (b) (4) and have concluded that the name is unacceptable for the following reasons.

The proposed proprietary name, (b) (4)

(b) (4)

Vigamot

(b) (4)

We note that you have proposed an alternate proprietary name in your submission dated June 8, 2010. In order to initiate the review of the alternate proprietary name, [REDACTED] (b) (4) [REDACTED] (b) (4) submit a new complete request for proprietary name review. The review of this alternate name will not be initiated until the new submission is received.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
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

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/s/

CAROL A HOLQUIST
09/08/2010

Gorski, Lori M

From: Gorski, Lori M
Sent: Wednesday, June 30, 2010 4:35 PM
To: 'Lankow,Karen,FORT WORTH,Regulatory Affairs'
Subject: NDA 22-428, Request from Statistical Reviewer

Hi Karen - The statistical reviewer on NDA 22-428, moxifloxacin, requests the following information. Please submit your response in triplicate via the Ammendale Rd. document control room. Please let me know if you have any questions.

Thanks.

Lori Gorski
Project Manager
Division of Anti-Infective & Ophthalmology Products
Phone 301-796-0722
Fax 301-796-9881
E-mail lori.gorski@fda.hhs.gov

In your datasets c0740_outcomes_, please differentiate the variables "clin_cure_vlmls" and "clin_cure_vls". Moreover, please specify the primary efficacy endpoint and define the Test-of-Cure Visit in contradistinction with the End-of-Therapy Visit.

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

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/s/

LORI M GORSKI
06/30/2010
stat request for info



NDA 22-428

ACKNOWLEDGE CLASS 2 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:

We acknowledge receipt on May 21, 2010, of your May 20, 2010, resubmission to your new drug application for Moxifloxacin AF (moxifloxacin hydrochloride ophthalmic solution) 0.5% as base.

We consider this a complete, class 2 response to our October 7, 2009, action letter. Therefore, the user fee goal date is November 21, 2010.

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

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
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

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/s/

MAUREEN P DILLON PARKER
06/30/2010



NDA 022428

**PROPRIETARY NAME REQUEST
UNACCEPTABLE**

Alcon Pharmaceuticals Ltd
c/o Alcon Research Ltd
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

ATTENTION: Karen Lankow
Associate Director, Regulatory Affairs

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%.

We also refer to your August 25, 2009, correspondence, received August 26, 2009, requesting review of your proposed proprietary name, (b) (4). We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following reasons.

(b) (4)

The name pair, (b) (4) and Kenalog, (b) (4)

(b) (4)

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, we recommend that you submit a new request for a proposed proprietary name review. (See the draft Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, [HTTP://www.fda.gov/cder/guidance/7935dft.pdf](http://www.fda.gov/cder/guidance/7935dft.pdf) and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
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

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/s/

CAROL A HOLQUIST
01/13/2010

Gorski, Lori M

From: Gorski, Lori M
Sent: Monday, October 05, 2009 9:00 AM
To: 'Lankow,Karen,FORT WORTH,Regulatory Affairs'
Subject: NDA 22-428 request from quality micro reviewer

Hi Karen -

Below is a request from the quality micro reviewer for Moxi AF. Please respond to the NDA. Call me if you have any questions. Thanks.

1. The specification for bacterial endotoxin (NMT (b) (4) while similar to some other Alcon topical ophthalmic drug products containing xanthan (b) (4) is higher than the expected limit of (b) (4) for such drug products. As part of the product's continual process improvement life cycle, establish a program to lower the acceptance criteria to NMT (b) (4)

(b) (4)

Lori Gorski
Project Manager
Division of Anti-Infective & Ophthalmology Products
Phone 301-796-0722
Fax 301-796-9881
E-mail lori.gorski@fda.hhs.gov

Address for mailing **official regulatory submissions.**
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective & Ophthalmology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Address for mailing **DESK COPIES to my attention.** This is our street address.
Food and Drug Administration
Division of Anti-Infective & Ophthalmology Products
10903 New Hampshire Avenue
Building #22 Room 6386
Silver Spring, MD 20993

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22428

ORIG-1

ALCON
PHARMACEUTICA
LS LTD

MOXIFLOXACIN ALTERNATIVE
FORMULATION OP

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/s/

LORI M GORSKI

10/05/2009

quality micro IR

For Internal Use Only

Meeting Request Granted Form**

(Use this form to document the meeting granted via telephone.)

Complete the information below and check form into DFS.

Application Type	P-IND	IND	NDA
Application Number			22428
DATE Sponsor informed of meeting granted	08/21/09		
Sponsor was informed of:			
<ul style="list-style-type: none"> • date/time & meeting location • expected FDA attendees • meeting briefing package due date • number of copies 	x Yes	No	
	xYes	No	
	Yes (date: _____)	No x	
	Yes	No x	
	Other: please indicate _____		
	This was a FDA initiated meeting		
Project Manager	Brantley Dorch		

Any follow-up letter must be checked into DFS as an advice letter, **NOT as a meeting request granted letter.

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

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/s/

BRANTLEY H DORCH
10/02/2009



NDA 22428

MEETING MINUTES

Alcon Pharmaceuticals Ltd
c/o Alcon Research Ltd
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

Attention: Karen Lankow
Associate Director, Regulatory Affairs

Dear Ms. Lankow:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moxifloxacin Hydrochloride Ophthalmic Solution, 0.5%.

We also refer to the telecon between representatives of your firm and the FDA on August 24, 2009. The purpose of the meeting was to discuss concerns about the proposed proprietary name (b) (4) (b) (4)

A copy of the official minutes of the telecon is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology (OSE) at (301) 796-0150.

Sincerely,
{See appended electronic signature page}

Denise Toyer, PharmD
Deputy Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Enclosure

MEMORANDUM OF MEETING MINUTES

Meeting Type: Type C
Meeting Date and Time: August 24, 2009; 3:00 – 3:30 PM EST
Meeting Location: WO Bldg 22, RM 4440
Application Number: 22-428
Product Name: (b) (4) (b) (4)
Indication: Treatment of bacterial conjunctivitis
Sponsor/Applicant Name: Alcon Research, Ltd

Meeting Chair: Denise Toyer
Meeting Recorder: Brantley Dorch

FDA ATTENDEES

Office of Surveillance and Epidemiology (OSE)
Denise Toyer, Deputy Director, DMEPA
Kristina Arnwine, Team Leader, DMEPA
Lori Cantin, Safety Evaluator, DMEPA
Darrell Jenkins, Safety Regulatory Project Manager, Team Leader

SPONSOR PARTICIPANTS

Alcon Research, Ltd.
Scott Corning - Marketing
Alex Long - Marketing
Angela Kothe - Regulatory Affairs
Karen S. Lankow – Associate Director, Regulatory Affairs

BACKGROUND:

The Division of Medication Error Prevention and Analysis (DMEPA) has evaluated the proposed proprietary name (b) (4) (b) (4) and found the name unacceptable because (b) (4) (b) (4)

MEETING OBJECTIVES:

- Discuss DMEPA's objection to the proposed proprietary name
- Discuss the sponsor's options regarding proposed proprietary name

DISCUSSION POINTS

(b) (4)

- If the Applicant would like us to start review on their alternate name, they can withdraw their proprietary name and submit a new proprietary name request. If the Applicant doesn't withdraw the (b) (4) (b) (4) proprietary name, FDA will issue a letter denying this name by the Proprietary Name PDUFA date of August 30, 2009.

ACTION ITEMS

- Sponsor will notify FDA no later than August 27, 2009, of their intent otherwise FDA will issue a letter to deny the name.

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

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/s/

DENISE P TOYER
10/02/2009

MEMORANDUM OF MEETING MINUTES

Meeting Type: FDA-Initiated Teleconference Meeting
Time: September 7, 2010; 3:30 PM – 4:00 PM EST
Meeting Location: WO Bldg 22, RM 4270
Application Type and Number: NDA 22428
Product Name: (b) (4)
Indication: Treatment of bacterial conjunctivitis
Sponsor/Applicant Name: Alcon Research, Ltd.

Meeting Chair: Kristina Toliver
Meeting Recorder: Brantley Dorch

FDA ATTENDEES

Office of Surveillance and Epidemiology (OSE)
Kristina Toliver, Team Leader, DMEPA
Lori Cantin, Safety Evaluator, DMEPA
Sean Bradley, Team Leader, Project Management Staff

SPONSOR PARTICIPANTS

Alcon Research, Ltd.
Angela Kothe, Senior Director, Regulatory Affairs
Karen Lankow, Associate Director, Regulatory Affairs

(b) (4)

BACKGROUND:

NDA 22428 is a Class 2 Resubmission in the Division of Anti-infective and Ophthalmology Products. The OND PDUFA date is November 21, 2010. The applicant submitted a request for proprietary name review on June 8, 2010, proposing the name,

(b) (4)

The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the proposed name, (b) (4) and found the name unacceptable (b) (4)

MEETING OBJECTIVES:

- Discuss DMEPA's objection to the proposed proprietary name
- Discuss the Applicant's options regarding their alternate name and options moving forward

DISCUSSION POINTS:

- FDA indicated that the proposed proprietary name, (b) (4) was unacceptable (b) (4)
- The Applicant asked for more details regarding the reasons for denial. (b) (4)
- (b) (4)
- FDA explained that a new request for proprietary name review would need to be submitted in order to initiate the review of the alternate proprietary name, (b) (4)
- FDA indicated that supporting data for, (b) (4) (b) (4) would also have to be submitted with the request to review the alternate name due to the modifier, (b) (4)
- The Applicant inquired about the kind of supporting data needed.
- FDA explained the data must demonstrate that the modifier is not ambiguous and error prone which can be achieved by testing the modifier using healthcare practitioners.
- The Applicant asked about the process for submitting the supporting data.
- FDA indicated that the data should be submitted with the request for proprietary name review.
- The Applicant asked would they have to withdraw the alternate name if they decided not to submit it for review.

- FDA indicated that would not be necessary and informed company of their options moving forward which are
 - to submit a new request for review proprietary name, (b) (4) (b) (4) with supporting data or
 - submit the root name Vigamox with a different modifier with supporting data or
 - submit a brand new name for proprietary name review or
 - submit a rebuttal for (b) (4) after the denial letter is received.

ACTION ITEMS:

- Applicant will take all of their options into consideration and will notify FDA of their intent.

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/s/

BRANTLEY H DORCH
09/29/2010



NDA 22-428

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Alcon Pharmaceuticals Ltd
c/o Alcon Research Ltd
Mail Code R3-52
6201 South Freeway
Fort Worth, Texas 76134-2099

Attention: Karen Lankow
Associate Director, Regulatory Affairs

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%.

We acknowledge receipt of your August 25, 2009, correspondence received August 26, 2009, notifying us that you are withdrawing your May 29, 2009, request for a review of the proposed proprietary name (b) (4) (b) (4). This proposed proprietary name request is considered withdrawn as of August 26, 2009.

We acknowledge that you have proposed an alternate proprietary name, (b) (4) in your submission dated August 25, 2009.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Lori Gorski at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
----- NDA 22428	----- ORIG 1	----- ALCON PHARMACEUTICA LS LTD	----- MOXIFLOXACIN ALTERNATIVE FORMULATION OP

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/s/

DENISE P TOYER on behalf of CAROL A HOLQUIST
08/27/2009

Gorski, Lori M

From: Gorski, Lori M
Sent: Thursday, June 25, 2009 8:44 AM
To: 'Lankow,Karen,FORT WORTH,Regulatory Affairs'
Subject: NDA 22-428 Moxifloxacin AF

Hi Karen -

Here is a request from the clinical micro reviewer for Moxi AF. Please respond to the NDA. Call me if you have any questions. Thanks.

1. Please provide copies of the Laboratory Investigator Manuals, referenced in Reports TDOC-0008133 and TDOC 0008134.
2. The Materials/Methods sections of Reports TDOC-0008133 and TDOC 0008134 do not discuss quality control procedures performed in the course of laboratory investigations (bacterial/viral identification, susceptibility testing, etc.). Please confirm that appropriate quality control was performed, and provide summary information concerning these procedures for all methods discussed in the reports.

Lori Gorski
Project Manager
Division of Anti-Infective & Ophthalmology Products
Phone 301-796-0722
Fax 301-796-9881
E-mail lori.gorski@fda.hhs.gov

Address for mailing **official regulatory submissions**.
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Center for Drug Evaluation and Research
Division of Anti-Infective & Ophthalmology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Address for mailing **DESK COPIES to my attention**. This is our street address.
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Division of Anti-Infective & Ophthalmology Products
10903 New Hampshire Avenue
Building #22 Room 6386
Silver Spring, MD 20903

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/s/

Lori Gorski
6/25/2009 08:50:05 AM
CSO



FILING COMMUNICATION

NDA 22-428

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 have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application is considered filed 60 days after the date we received your application in accordance with 21 CFR 314.101(a). The review classification for this application is **Standard**. Therefore, the user fee goal date is October 15, 2009.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to initiate discussion on the proposed labeling and, if necessary, any postmarketing commitment requests by September 2, 2009.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

If you have any questions, call Lori Gorski, Regulatory Health 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

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/s/

Wiley Chambers
2/26/2009 12:25:57 PM

Fax



**Division of Anti-Infective and
Ophthalmology Products**
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

To: Karen Lankow, Alcon

From: Lori Gorski, Project Manager

Fax: sent via email

Fax: 301-796-9881

Phone: 817-551-6494

Phone: 301-796-0722

Pages: 2 (including cover page)

Date: February 3, 2009

Re: Reviewer comments and requests for NDA 22-428 Moxifloxacin AF dated December 12, 2008

Urgent For Review Please Comment Please Reply Please Recycle

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

● **Comments:**

Karen,

Attached are the Divisions comments from the original submission of NDA 22-428.

Please respond with an official submission through the document control room. If you have any questions, please contact me.

Lori Gorski

NDA 22-428

Submission Date: December 12, 2008
Received Date: December 15, 2008

Sponsor Alcon Research, Ltd
6201 South Freeway
Fort Worth, Texas 76134

Drug Moxifloxacin AF (moxifloxacin hydrochloride ophthalmic solution) 0.5%

Sterility Micro

1. The bacterial endotoxin acceptance criterion for the drug product release was MNT (b) (4) (equivalent to Less Than (b) (4) The criterion should be formally stated as EU/ml and not EU/dose. Please submit a correction.

CMC

2. Please update the application with all CFN/FEI numbers and confirm establishment addresses. If this information has already been submitted in the NDA please give a location where it can be found.

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/s/

Lori Gorski
5/11/2009 02:39:20 PM
CSO

Lori Gorski
5/11/2009 02:39:43 PM
CSO

NDA FILEABILITY CHECKLIST

NDA Number: 22-248

Applicant: Alcon Research Ltd

Letter Date: December 12, 2008

Stamp Date: December 13, 2008

Drug Name: Moxifloxacin AF (moxifloxacin hydrochloride Ophthalmic Solution) 0.5%

IS THE CMC SECTION OF THE APPLICATION FILEABLE? (Yes or No) Yes

The following parameters are necessary in order to initiate a full review, i.e., complete enough to review but may have deficiencies.

	Parameter	Yes	No	Comment
1	On its face, is the section organized adequately?	Y		
2	Is the section indexed and paginated adequately?	Y		This is a hard copy NDA
3	On its face, is the section legible?	Y		
4	Are ALL of the facilities (including contract facilities and test laboratories) identified with full <u>street</u> addresses and CFNs?	Y		Not complete CFN list
5	Is a statement provided that all facilities are ready for GMP inspection?	Y		In summary sheet
6	Has an environmental assessment report or categorical exclusion been provided?	Y		
7	Does the section contain controls for the drug substance?	Y		Moxifloxacin HCl supplied by Bayer HealthCare AG. Ref: NDA 21-085
8	Does the section contain controls for the drug product?	Y		
9	Has stability data and analysis been provided to support the requested expiration date?	Y		One strength with 2 fill sizes of 1 mL and 3 mL. 3 batches 12 months stability RT and 6 months accelerated for all fill sizes, horizontal and upright, provided.
10	Has all information requested during the IND phase, and at the pre-NDA meetings been included?			This is an alternate formulation of an approved drug product
11	Have draft container labels been provided?	Y		No mock-up provided
12	Has the draft package insert been provided?	Y		
13	Has an investigational formulations section been provided?	Y		
14	Is there a Methods Validation package?		N	Stated to be in 3.2.R.3 but missing
15	Is a separate microbiological section included?	Y		

NDA 22-248

Chemistry Reviewer:
Pharmaceutical Assessment Lead:
Branch Chief:
Prepared by: LN & BS 1/26/09

Bala Shanmugan, Ph.D.
Linda Ng, Ph.D.
Norman Schmuff, Ph.D.

DMF Number	Holder	Description	LOA Included	Status
NDA 21-085	Bayer HealthCare AG	Moxifloxacon HCl	August 27, 2008	
(b) (4)	(b) (4)	(b) (4)	May 20, 2008	
(b) (4)	(b) (4)	(b) (4)	August 11, 2008	
(b) (4)	(b) (4)	(b) (4)	August 6, 2008	

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/s/

Linda Ng
1/27/2009 12:37:58 PM
CHEMIST

Norman Schmuff
1/29/2009 06:04:55 PM
CHEMIST



NDA 22-428

NDA ACKNOWLEDGMENT

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

Dear Ms. Lankow:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug Product: Moxifloxacin AF (moxifloxacin hydrochloride ophthalmic solution)
0.5% as base

Date of Application: December 12, 2008

Date of Receipt: December 15, 2008

Our Reference Number: NDA 22-428

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on February 13, 2009, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective and Ophthalmology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>.

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

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

Maureen Dillon-Parker
1/23/2009 05:18:37 PM