CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208582Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # 208582 BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type: *(an action package is not required for SE8 or SE9 supplements)*
Proprietary Name: Altafluor Benox Established/Proper Name: fluorescein sodium and benoxinate hydrochloride Dosage Form: ophthalmic solution		Applicant: Alcon Research, ltd. Agent for Applicant (if applicable):
RPM: Michael Puglisi		Division: DTOP

NDA Application Type: ☐ 505(b)(1) ☒ 505(b)(2)
Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2)

BLA Application Type: ☐ 351(k) ☐ 351(a)
Efficacy Supplement: ☐ 351(k) ☐ 351(a)

For ALL 505(b)(2) applications, two months prior to EVERY action:

- **Review the information in the 505(b)(2) Assessment and submit the draft[2] to CDER OND IO for clearance.**
- **Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)**

☒ No changes
☐ New patent/exclusivity *(notify CDER OND IO)*
Date of check:

Note: 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.

Actions	
• Proposed action • User Fee Goal Date is 12/28/17	☒ AP ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☐ None CR - 6/22/16
❖ 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 ____	☐ Received
❖ Application Characteristics[3]	

[1] The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.

[2] For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).

[3] 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.

Reference ID: 4200272

Review priority: ☐ Standard ☒ Priority
Chemical classification (new NDAs only):
(confirm chemical classification at time of approval)

☐ Fast Track
☐ Rolling Review
☐ Orphan drug designation
☐ Breakthrough Therapy designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

(NOTE: Set the submission property in DARRTS and notify the CDER Breakthrough Therapy Program Manager; Refer to the "RPM BT Checklist for Considerations after Designation Granted" for other required actions: CST SharePoint)

NDAs: Subpart H
☐ Accelerated approval (21 CFR 314.510)
☐ Restricted distribution (21 CFR 314.520)
Subpart I
☐ Approval based on animal studies

BLAs: Subpart E
☐ Accelerated approval (21 CFR 601.41)
☐ Restricted distribution (21 CFR 601.42)
Subpart H
☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC
☐ Submitted in response to a Pediatric Written Request

REMS: ☐ MedGuide
☐ Communication Plan
☐ ETASU
☐ MedGuide w/o REMS
☐ REMS not required

Comments:

❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☒ Yes ☐ No
• Indicate what types (if any) of information were issued	☒ None ☐ FDA Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other
❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type	☒ No ☐ Yes
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	☒ Verified ☐ Not applicable because drug is an old antibiotic.

CONTENTS OF ACTION PACKAGE

Officer/Employee List

❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included

Action Letters	
Copies of all action letters *(including approval letter with final labeling)*	CR- 6/22/16 AP- 12/14/17
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☒ Included in AP letter
• Original applicant-proposed labeling	☒ Included
❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☒ None
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ Included
• Original applicant-proposed labeling	☐ Included
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	☒ Included in AP letter
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s)*	Letters- 4/21/16, 9/22/17, 12/12/17 Reviews- 4/21/16, 9/22/17, 12/8/17
❖ Labeling reviews *(indicate dates of reviews)*	RPM: ☒ None DMEPA: ☐ 6/2/16, 10/6/17 DMPP/PLT (DRISK): ☒ None OPDP: ☐ 6/13/16, 12/12/17 SEALD: ☒ None CSS: ☒ None Product Quality ☒ None Other: ☐ ADL– 9/11/17
Administrative / Regulatory Documents	
❖ RPM Filing Review[4]/Memo of Filing Meeting *(indicate date of each review)* ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	6/22/16 ☐ Not a (b)(2) 10/27/17
❖ NDAs/NDA supplements only: Exclusivity Summary *(signed by Division Director)*	☒ Completed
❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No

[4] Filing reviews for scientific disciplines are NOT required to be included in the action package.

• This application is on the AIP o If yes, Center Director's Exception for Review memo *(indicate date)* o If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes ☒ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC If PeRC review not necessary, explain: _____	5/11/16
❖ Breakthrough Therapy Designation	☒ N/A
• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)	
• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) *(include only the completed template(s) and not the meeting minutes)*	
• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) *(include only the completed template(s) and not the meeting minutes)* *(completed CDER MPC templates can be found in DARRTS as clinical reviews or on the MPC SharePoint Site)*	
❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, Formal Dispute Resolution Request decisional letters, etc.) *(do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include Master File letters; do not include previous action letters, as these are located elsewhere in package)*	Included in Package
Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes)	N/A
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☒ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☐ No mtg 8/26/13, 6/16/15
• EOP2 meeting *(indicate date of mtg)*	☒ No mtg
• Mid-cycle Communication *(indicate date of mtg)*	☒ N/A
• Late-cycle Meeting *(indicate date of mtg)*	☒ N/A
• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) *(indicate dates of mtgs)*	
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None 6/22/16, 12/14/17
Cross-Discipline Team Leader Review *(indicate date for each review)*	☐ None 6/17/16, 12/14/17
PMR/PMC Development Templates *(indicate total number)*	☒ None
Clinical	

❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	☒ No separate review
• Clinical review(s) *(indicate date for each review)*	3/1/16, 5/25/16, 10/12/17
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☒ and include a review/memo explaining why not *(indicate date of review/memo)*	Addressed in 5/25/16 Clinical Review
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*[5]	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ N/A
❖ Risk Management • REMS Documents and REMS Supporting Document *(indicate date(s) of submission(s))* • REMS Memo(s) and letter(s) *(indicate date(s))* • Risk management review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)*	☒ None
❖ OSI Clinical Inspection Review Summary(ies) *(include copies of OSI letters to investigators)*	☒ None requested
Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☐ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☒ No separate review
Statistical Team Leader Review(s) *(indicate date for each review)*	☒ No separate review
Statistical Review(s) *(indicate date for each review)*	☐ None 3/9/16
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☒ No separate review
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ No separate review
Clinical Pharmacology review(s) *(indicate date for each review)*	☐ None 2/3/16, 4/7/16
❖ OSI Clinical Pharmacology Inspection Review Summary *(include copies of OSI letters)*	☒ None requested

or Part 3 combination products, all reviews from the reviewing Center(s) should be entered into the official archive (for further instructions, see "Section 508 Compliant Documents: Process for Regulatory Project Managers" located in the CST electronic repository).

Nonclinical ☐ None	
Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☒ No separate review
• Supervisory Review(s) *(indicate date for each review)*	☒ No separate review
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	☐ None 2/2/16, 6/8/16, 6/23/16
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☒ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☒ No carc
❖ ECAC/CAC report/memo of meeting	☒ None Included in P/T review, page
❖ OSI Nonclinical Inspection Review Summary *(include copies of OSI letters)*	☒ None requested
Product Quality ☐ None	
❖ Product Quality Discipline Reviews[6]	
• Tertiary review (*indicate date for each review*)	☒ None
• Secondary review (e.g., Branch Chief) *(indicate date for each review)*	☒ None
• Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) *(indicate date for each review)*	☐ None 5/22/16, 5/26/16, 6/15/16, 11/28/17
❖ Reviews by other disciplines/divisions/Centers requested by product quality review team *(indicate date of each review)*	☒ None
Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	In 5/22/16, Integrated Review
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ Facilities Review/Inspection	
☐ Facilities inspections (indicate date of recommendation; within one week of taking an approval action, confirm that there is an acceptable recommendation) *(only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)*	☒ Acceptable Re-evaluation date: ☐ Withhold recommendation. ☐ Not applicable

[6] Do not include Master File (MF) reviews or communications to MF holders. However, these documents should be made available upon signatory request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Altaire Pharmaceuticals, Inc.
PO Box 849
311 West Lane
Aquebogue, NY 11931

ATTENTION: Michael Sawaya
General Counsel

Dear Mr. Sawaya:

Please refer to your New Drug Application (NDA) dated and received June 28, 2017, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%.

We also refer to your correspondence dated and received September 29, 2017, requesting review of your proposed proprietary name, Altafluor Benox.

We have completed our review of the proposed proprietary name, Altafluor Benox and have concluded that it is conditionally acceptable.

If any of the proposed product characteristics as stated in your above submissions are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review. Additionally, if your application receives a complete response, a new request for name review for your proposed name should be submitted when you respond to the application deficiencies.

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022, (https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Abiola Olagundoye-Alawode, PharmD, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3982. For any other information regarding this application, contact Michael Puglisi, Regulatory Project Manager in the Office of New Drugs, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
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/

DANIELLE M HARRIS on behalf of TODD D BRIDGES
12/12/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

PROPRIETARY NAME ACKNOWLEDGEMENT

Altaire Pharmaceuticals, Inc.
PO Box 849
311 West Lane
Aquebogue, NY 11931

ATTENTION: Michael Sawaya
General Counsel

Dear Mr. Sawaya:

Please refer to your New Drug Application (NDA) dated and received June 28, 2017, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%.

We acknowledge receipt of your correspondence, dated and received September 29, 2017, requesting a review of your proposed proprietary name, Altafluor Benox.

The target date for your proprietary name review is December 28, 2017.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Abiola Olagundoye-Alawode, PharmD, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3982. For any other information regarding this application, contact Michael Puglisi, Regulatory Project Manager, in the Office of New Drugs at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Abiola Olagundoye-Alawode, PharmD, MS
LCDR, USPHS
Safety Regulatory Project Manager
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/

ABIOLA M OLAGUNDOYE-ALAWODE
10/25/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

PROPRIETARY NAME REQUEST
UNACCEPTABLE

Altaire Pharmaceuticals, Inc.
PO Box 849
311 West Lane
Aquebogue, NY 11931

ATTENTION: Michael Sawaya
General Counsel

Dear Mr. Sawaya:

Please refer to your New Drug Application (NDA) dated and received June 28, 2017, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%.

We also refer to your correspondence, dated and received June 28, 2017, 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:

We note that your product contains the active ingredients, fluorescein sodium and benoxinate hydrochloride. One of the active ingredients, fluorescein sodium, is represented in the suffix of the proprietary name ('fluor'), whereas the other active ingredient, benoxinate hydrochloride, is not suggested or included in the proposed proprietary name.

Therefore, the proposed name, (b) (4) is misleading pursuant to 21 CFR 201.6(b) which states:

> *The labeling of a drug which contains two or more ingredients may be misleading by reason,among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.*

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.

If you require additional information on developing proprietary names for drugs, proposing alternative proprietary names for consideration, or requesting reconsideration of our decision, we refer you to the following:

- Draft Guidance for Industry Best Practices in Developing Proprietary Names for Drugs, (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf)
- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Abiola Olagundoye-Alawode, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3982. For any other information regarding this application, contact Michael Puglisi, Regulatory Project Manager in the Office of New Drugs, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
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/

DANIELLE M HARRIS on behalf of TODD D BRIDGES
09/22/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

ACKNOWLEDGE –
CLASS 2 RESUBMISSION

Altaire Pharmaceuticals, Inc.
Attention: Michael S. Sawaya
General Counsel
P.O. Box 849
311 West Lane
Aquebogue, NY 11931

Dear Mr. Sawaya:

We acknowledge receipt on June 28, 2017, of your resubmission to your supplemental new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for (b) (4) (fluorescein sodium and benoxinate hydrochloride ophthalmic solution), 0.25%/0.4%.

We consider this a complete, Class 2 response to our June 22, 2016, action letter. Therefore, the user fee goal date is December 28, 2017.

If you have any questions, please call me at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Michael Puglisi
Regulatory Project Manager
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
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/

MICHAEL J PUGLISI
07/17/2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 208582

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Altaire Pharmaceuticals, Inc.
PO Box 849
311 West Lane
Aquebogue, NY 11931

ATTENTION: Michael Sawaya
General Counsel

Dear Mr. Sawaya:

Please refer to your New Drug Application (NDA) dated December 22, 2015, received December 22, 2015, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%.

We also refer to your January 22, 2016, correspondence, received January 27, 2016, 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 it is conditionally acceptable.

If any of the proposed product characteristics as stated in your January 22, 2016, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)

- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Janet Higgins, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (240) 402-0330. For any other information regarding this application, contact Michael Puglisi, Regulatory Project Manager in the Office of New Drugs, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
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/

TODD D BRIDGES
04/21/2016

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products
Division of Transplant and Ophthalmology Products

Review Comments Transmittal

DATE: 3/23/16

To: Michael Sawaya	**From: Michael Puglisi** **Regulatory Project Manager**
	e-mail: Michael.puglisi@fda.hhs.gov
e-mail: mssawaya@aol.com	**Phone Number: 301-796-0791**
Phone Number: **631-722-5988**	

Subject: Information Request for NDA 208582

Total no. of pages including cover: **2**

Comments:

Dear Mr. Sawaya,

Attached please find an information request concerning NDA 208582 for (b) (4) which was submitted on December 22, 2015. Please let me know if you have any questions about the comments. Thanks.

Mike Puglisi
Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Transplant and
Ophthalmology Products
phone - 301-796-0791
fax - 301-796-9881

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 this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at 301-796-1600. Thank you.

Review Comments:
We are continuing the review of your NDA 208582 for [redacted] *(fluorescein sodium and benoxinate hydrochloride ophthalmic solution). We recently sent an information request regarding the manufacturing of your product,* [redacted]

In addition, your 505(b)(2) application is relying on published studies, some from as far back as the 1960s. To augment your NDA with more current information on utilization and extent of patient exposure, please provide the following information (We acknowledge your statement in Module 2.5 that Altaire as a contract manufacturer and distributor of the combination product, has sold approximately [redacted] *units since 2005, but request more detail.):*

a. *Provide the extent of patient use of your product annually (number of vials or other approximation) over the past 10-20 years, including what percentage of patients receiving benoxinate hydrochloride/fluorescein sodium combination received the Altaire product, as well as product manufactured by Altaire distributed by other company(ies).*

b. *Provide information on any post-marketing adverse event reporting for your Altaire product in the last two decades.*

a. *Please identify in the application where you provide a list of the publications reporting specifically on testing of the Altaire product (versus other manufacturers). You stated in the Pre-IND meeting package for the March 26, 2015 meeting (IND 118845)* [redacted] *therefore identify publications that report on* [redacted] *as well as those reporting on* [redacted] *If you are contract manufacturer for product distributed by other companies as well, please identify articles reporting on those products.*

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

/s/

MICHAEL J PUGLISI
03/23/2016

Puglisi, Michael

From: Puglisi, Michael
Sent: Wednesday, March 09, 2016 9:58 AM
To: 'mssawaya@aol.com'
Subject: FDA - Nonclinical Information Request for (b) (4) NDA - NDA 208582

Importance: High

Hi Michael,

Below please find information requests from our Nonclinical reviewer for the (b) (4) NDA, which was submitted on December 22, 2015. Please confirm receipt and let me know if you have any questions about anything. Thanks.

Mike Puglisi
Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Transplant and
Ophthalmology Products
phone - 301-796-0791
fax - 301-796-9881

Reviewer's Comment:

(b) (4)

Reference ID: 3899110

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

/s/

MICHAEL J PUGLISI
03/09/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED

Altaire Pharmaceuticals, Inc.
Attention: Michael Sawaya
General Counsel
311 West Lane
Aquebogue, NY 11931

Dear Mr. Sawaya:

Please refer to your New Drug Application (NDA) dated and received December 22, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for (b) (4) (fluorescein sodium and benoxinate hydrochloride ophthalmic solution USP), 0.25%/0.4%

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application will be considered filed 60 days after the date we received your application. The review classification for this application is **Priority**. Therefore, the user fee goal date is June 22, 2016**.**

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 communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by the week of May 30, 2016, approximately.

At this time, we are notifying you that, we have not identified any potential review issues. Please note that our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

PRESCRIBING INFORMATION
Your proposed prescribing information (PI) must conform to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57. As you develop your proposed PI, we encourage

you to review the labeling review resources on the *PLR Requirements for Prescribing Information* and *PLLR Requirements for Prescribing Information* websites including:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information in the PI on pregnancy, lactation, and females and males of reproductive potential
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents
- The Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances and
- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

At the end of labeling discussions, use the SRPI checklist to ensure that the PI conforms with format items in regulations and guidances.

PROMOTIONAL MATERIAL

You may request advisory comments on proposed introductory advertising and promotional labeling. Please submit, in triplicate, a detailed cover letter requesting advisory comments (list each proposed promotional piece in the cover letter along with the material type and material identification code, if applicable), the proposed promotional materials in draft or mock-up form with annotated references, and the proposed package insert (PI). Submit consumer-directed, professional-directed, and television advertisement materials separately and send each submission to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

Do not submit launch materials until you have received our proposed revisions to the package insert (PI), and you believe the labeling is close to the final version.

For more information regarding OPDP submissions, please see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm. If you have any questions, call OPDP at 301-796-1200.

REQUIRED PEDIATRIC ASSESSMENTS

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We note that you have submitted pediatric studies with this application, and you have not requested a partial waiver or deferral for any additional studies. Once the review of this application is complete, we will notify you whether you have fulfilled the pediatric study requirement for this application.

If you have any questions, call Michael Puglisi, Regulatory Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
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/

WILEY A CHAMBERS
02/19/2016

Puglisi, Michael

From: Puglisi, Michael
Sent: Thursday, February 04, 2016 2:15 PM
To: mssawaya@aol.com
Subject: Quality and Nonclinical Information Requests for (b) (4) NDA - NDA 208582

Hi Michael,

Below please find information requests from our Quality and Nonclinical reviewers for the (b) (4) NDA, which was submitted on December 22, 2015. Please confirm receipt and let me know if you have any questions about anything. Thanks.

Mike Puglisi
Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Transplant and
Ophthalmology Products
phone - 301-796-0791
fax - 301-796-9881

Quality Reviewer's Comments:
For the drug product specifications, use either one specific identity method or two non-specific tests for the active ingredients (see ICH Q6A). For example, two chromatographic procedures,
where separation is based on different principles, or a combination of tests into a single procedure, such as HPLC/UV diode array, are generally acceptable.

Nonclinical Reviewer's Comments:
The literature citations given for Section 2.4.4.1.2 Repeated Dose Studies are not related to the studies summarized. These should be revised and the correct publications provided. The LD50
values provided for benoxinate hydrochloride in the table under Section 2.4.4.2.1 Single Dose Studies could not be confirmed from the values reported in the reference provided. Please
provide further details of the source of the information.

Reference ID: 3882942

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

/s/

MICHAEL J PUGLISI
02/04/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208582

NDA ACKNOWLEDGMENT

Altaire Pharmaceuticals, Inc.
Attention: Michael Sawaya
General Counsel
311 West Lane
Aquebogue, NY 11931

Dear Mr. Sawaya:

We have received your New Drug Application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%

Date of Application: December 22, 2015

Date of Receipt: December 22, 2015

Our Reference Number: NDA 208582

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 20, 2016, 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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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.

You are also responsible for complying with the applicable provisions of sections 402(i) and 402(j) of the Public Health Service Act (PHS Act) [42 USC §§ 282 (i) and (j)], which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No, 110-85, 121 Stat. 904).

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 Transplant and Ophthalmology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you have any questions, please call me at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Michael Puglisi
Regulatory Project Manager
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
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/

MICHAEL J PUGLISI
01/15/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

PIND 118845

MEETING MINUTES

Altaire Pharmaceuticals, Inc.
Attention: Mr. Michael Sawaya
General Counsel
P.O. Box 849
311 West Lane
Aquebogue, N.Y. 11931

Dear Mr. Sawaya:

Please refer to your Pre-Investigational New Drug Application (PIND) file for fluorescein sodium and benoxinate hydrochloride ophthalmic solution, 0.25%/0.4%.

The purpose of the June 16, 2015, meeting was to discuss the development of a fluorescein sodium and benoxinate hydrochloride ophthalmic solution product. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Jacquelyn Smith, M.A., Senior Regulatory Project Manager at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Meeting Minutes

MEMORANDUM OF MEETING MINUTES

Meeting Date: June 16, 2015

Meeting Type: Type B, Pre-NDA

Application: PIND 118845

Drug: Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP (0.25%/0.4%)

Sponsor: Altaire Pharmaceuticals, Inc.

Proposed Indication: For ophthalmic procedures requiring a disclosing agent in combination with an anesthetic agent (b) (4) (b) (4)

FDA Participants:

Renata Albrecht, M.D.	Director, DTOP
Wiley Chambers, M.D.	Deputy Director, DTOP
Anamitro Banerjee, Ph.D.	Chemistry Team Lead, OPQ/ONDP/DNDPI/NDPBIII
Lori Kotch, Ph.D.	Pharmacology/Toxicology Team Lead, DTOP
Maria Rivera, Ph.D.	Pharmacology/Toxicology Reviewer, DTOP
William Boyd, M.D.	Clinical Team Leader, DTOP
Philip M. Colangelo, Pharm.D., Ph.D.	Clinical Pharmacology Team Leader, OTS/OCP/DCPIV
Yongheng Zang, Ph.D.	Clinical Pharmacology Reviewer, OTS/OCP/DCPIV
Yunfan Deng, Ph.D.	Statistics Reviewer, OTS/OB/DBIV
Yan Wang, Ph.D.	Statistics Team Leader, OTS/OB/DBIV
Jacquelyn Smith, M.A.	Senior Regulatory Project Manager, DTOP

Sponsor Participants

Michael Sawaya	General Counsel, Altaire Pharmaceuticals, Inc. (b) (4)

Background:

On May 14, 2015, Altaire Pharmaceuticals, Inc. (Altaire) submitted a meeting package for the fluorescein sodium and benoxinate hydrochloride ophthalmic solution product. Meeting was scheduled for June 16, 2015. On June 12, 2015, the Agency provided, via e-mail, preliminary comments to the questions outlined in the briefing package by Altaire. Altaire responded, via

June 16, 2015 email, that after receipt of the preliminary comments, questions 3, 9, 11, and Additional Comment 1, needed further clarification. The questions outlined in the meeting package are presented in bold font, FDA responses are presented in italic format and meeting discussion is in normal font.

Preliminary comments

1. **Since it was specifically stated at the meeting and in the meeting minutes that "the information you have provided in the briefing package are not adequate to support the safety and efficacy of the proposed drug product," does the Agency concur that the literature-based efficacy and safety information presented now is sufficient to allow for filing and review of the NDA?**

   Agency Response: The information provided in the meeting package appears adequate to support the filing and review of an NDA.

   No discussion was needed.

2. **Does the Agency agree with Altaire's proposal that, given the literature-based efficacy and safety information presented, no further nonclinical studies are necessary to support the safety and efficacy of Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution?**

   Agency Response: We do not anticipate additional nonclinical studies will be necessary, presuming that no safety issues emerge related to the proposed formulation.

   No discussion was needed.

3. **Does the Agency agree with Altaire's proposal that, given the literature-based efficacy and safety information presented, no further clinical studies are necessary to support the safety and efficacy of Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution?**

   Agency Response: Provided you can give us an adequate bridge between the formulations described in the literature and the formulation you intend to market, we would not anticipate the need for an additional clinical study.

   Meeting Discussion:
   Altaire asked for clarification because they believe the literature-based efficacy and safety information they presented forms an adequate bridge. The Agency clarified that the Agency response (above) was provided to simply reiterate that an adequate bridge between the literature and the formulation intended for market will need to be included in the NDA submission.

4. Does the Agency agree with the proposed indications listed in Section 3.0?

Agency Response: *Labeling is a review issue. The language for the "Indication Section" of the labeling will be determined when the NDA is reviewed.*

No discussion was needed.

5. Does the Agency agree with the proposed dosing regimens listed in Section 4.0?

Agency Response: *Labeling is a review issue. The language for the "Dosing Regimen" of the labeling will be determined when the NDA is reviewed.*

No discussion was needed.

6. Does the Agency have any additional comments or guidance on this proposal?

Agency Response: *We recommend that you organize the literature that you intend to submit by 1) adequate and well-controlled trial vs. supportive data, 2) study population (i.e.., neonates, infants, adolescents, or adults) and 3) procedure that was performed using the drug product.*

No discussion was needed.

7. Does the Agency concur with Altaire's proposal that the concentrations of Chlorobutanol and Povidone in the proposed drug product are supported by the information summarized above and that no nonclinical toxicology studies are required to support the NDA?

Agency Response: We concur.

No discussion was needed.

8. The following marketing/regulatory conditions exist for the proposed new drug Application, and form the basis for Altaire's request for a Priority Review for the NDA:

- **There are currently no fluorescein/anesthetic ophthalmic combination products that are currently approved under a new drug application;**
- **As stated in the Unapproved Drug Initiative in 2006, the Agency's position is that it is important to have all DESI-related products approved under a new drug application. While unapproved versions exist in the marketplace and the Agency has exercise some enforcement discretion in this regard, the formal regulatory approval of this product is especially important since it is a sterile dosage form intended for application to the eyes; and**
- **An unmet medical need exists since there are no FDA-approved ophthalmic products for a disclosing agent in combination with an anesthetic agent, and approving this drug product would provide a therapeutic agent where none currently exists for use in the diagnosis of serious conditions where early diagnosis results in an improved outcome.**

Does the Agency concur that the above represents a reasonable basis for a priority review of the NDA?

Agency Response: *The assignment of a standard or priority review clock is made at the time of NDA submission and filing. Since your proposed drug product does not treat a serious or life threatening disease, it is unlikely that your NDA will be assigned a priority review clock.*

No discussion was needed.

9. **Does the Agency agree that** (b) (4) (b) (4)

Agency Response: No. (b) (4) (b) (4)

Meeting Discussion: (b) (4) (b) (4)

Agency Response: *See response to Question 9.*

No discussion was needed.

11. **Does the Agency agree with Altaire's proposal that, given the initial pediatric assessment presented, this product may be appropriately labeled for use in all relevant pediatric populations (based on information from published studies) and therefore no additional pediatric studies are needed at this time?**

Agency Response: *Potentially. Labeling is a review issue. The language for the "Pediatric Use" section of the labeling will be determined when the NDA is reviewed.*

Meeting Discussion:
The Agency reiterated that labeling is a review issue and a determination made during the NDA review cycle. The Agency further referred Altaire to discussion of Question 9.

Additional Comments:

(b) (4)

[redacted]

2. *The NDA submission should include a summary of all published nonclinical literature being relied upon to support the NDA and a copy of all the publications cited.*

   All required nonclinical elements should be provided, either directly (original studies or published literature) or by relying on the FDA's findings of safety and effectiveness for a listed drug or published literature and establishing an adequate bridge to the listed drug or published literature. See Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals for further information regarding required nonclinical elements.

   (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073246.pdf)

   Impurity specifications that exceed qualification limits specified in the ICHQ3 guidances should be adequately qualified and the supporting safety data should be provided in the NDA submission. Ensure that ocular and systemic safety is addressed.

No discussion was needed.

Minutes Preparer: Jacquelyn Smith, M.A., Senior Regulatory Project Manager, DTOP
Chair Concurrence: Wiley Chambers, M.D., Deputy Director, DTOP

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
07/15/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

PIND 118845

MEETING MINUTES

Altaire Pharmaceuticals, Inc.
Attention: Mr. Michael Sawaya
General Counsel
P.O. Box 849
311 West Lane
Aquebogue, N.Y. 11931

Dear Mr. Sawaya:

Please refer to your Pre-Investigational New Drug Application (PIND) file for fluorescein sodium and benoxinate hydrochloride ophthalmic solution, 0.25%/0.4%.

The purpose of the August 26, 2013, meeting was to discuss the fluorescein sodium and benoxinate hydrochloride ophthalmic solution product. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Jacquelyn Smith, M.A., Senior Regulatory Project Manager at 301 796-1600.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Meeting Minutes
Stability Summary Table

MEMORANDUM OF MEETING MINUTES

Meeting Date: August 26, 2013

Meeting Type: Type B

Application: PIND 118845

Drug: Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP (0.25%/0.4%)

Sponsor: Altaire Pharmaceuticals, Inc.

Indication: For ophthalmic procedures requiring a disclosing agent in combination with an anesthetic agent (b) (4) (b) (4)

FDA Participants:

Renata Albrecht, M.D.	Director, DTOP
Wiley Chambers, M.D.	Deputy Director, DTOP
Balajee Shanmugam, Ph.D.	Chemistry Team Leader, OPS/ONDQA/DNDQAII/BRV
Steven Donald, Ph.D.	Quality Microbiology Reviewer, OPS/NDMS
Lori Kotch, Ph.D.	Pharmacology/Toxicology Team Lead, DTOP
Maria Rivera, Ph.D.	Pharmacology/Toxicology Reviewer, DTOP
William Boyd, M.D.	Clinical Team Leader, DTOP
Lucious Lim, M.D.	Clinical Reviewer, DTOP
Rhea Lloyd, M.D.	Clinical Reviewer, DTOP
Jennifer Harris, M.D.	Clinical Reviewer, DTOP
Philip M. Colangelo, Pharm.D., Ph.D.	Clinical Pharmacology Team Leader, OTS/OCP/DCPIV
Yongheng Zang, Ph.D.	Clinical Pharmacology Reviewer, OTS/OCP/DCPIV
Solomon Chefo, Ph.D.	Statistics Reviewer, OTS/OB/DBIV
Yan Wang, Ph.D.	Statistics Team Leader, OTS/OB/DBIV
Jacquelyn Smith, M.A.	Senior Regulatory Project Manager, DTOP

Sponsor Participants

Michael Sawaya	General Counsel, Altaire Pharmaceuticals, Inc.
Christine Miller, Pharm.D	(b) (4)

Purpose of the meeting:

The purpose of the August 26, 2013, meeting was to discuss the fluorescein sodium and benoxinate hydrochloride ophthalmic solution product.

Background:

On June 6, 2013 Altaire Pharmaceuticals, Inc. (Altaire) submitted a meeting package for the fluorescein sodium and benoxinate hydrochloride ophthalmic solution product. Meeting was scheduled for August 26, 2013. On August 22, 2013, FDA provided, via e-mail, preliminary comments to the questions outlined in the briefing package by Altaire. On August 25, 2013 Altaire responded, via email, that after receipt of the preliminary comments, there were four remaining items that needed clarification (questions 1, 8, 9 and 12. Also attached to the August 25, 2013 email was Altaire's stability summary table (attached below). The questions outlined in the meeting package are presented in bold font and FDA responses are presented in italic format.

Preliminary comments

(b) (4)

10 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

---

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
09/19/2013