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APPLICATION NUMBER:

206276Orig1s000

OTHER REVIEW(S)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
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CLINICAL INSPECTION SUMMARY

DATE: January 2, 2015

TO: Lois Almoza, Regulatory Project Manager
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Division of Topical and Ophthalmic Products

FROM: Roy Blay, Ph.D.
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SUBJECT: Evaluation of Clinical Inspections

NDA: 206276

APPLICANT: Alcon Research, Ltd.

DRUG: Olopatadine ophthalmic solution, 0.7%

NME: No

THERAPEUTIC CLASSIFICATION: Priority Review

INDICATION: Treatment of ocular itching

CONSULTATION REQUEST DATE: September 9, 2014
CLINICAL INSPECTION SUMMARY DATE: January 9, 2015
DIVISION ACTION GOAL DATE: January 30, 2015
PDUFA DATE: January 30, 2015

I. BACKGROUND:

The Applicant submitted this NDA to support the use of olopatadine ophthalmic solution, 0.7%, for the treatment of ocular itching.

The pivotal studies, C-10-126 entitled, "A Multicenter, Randomized, Double-Masked, Vehicle and Active Controlled, Parallel-Group Efficacy and Safety Study of AL-4943A Ophthalmic Solution, 0.77% in Patients with Allergic Conjunctivitis Using the Conjunctival Allergen Challenge (CAC) Model", and C-12-028 entitled "A Multicenter, Randomized, Double-Masked, Vehicle-Controlled, Parallel-Group Study Evaluating the Safety of AL-4943A Ophthalmic Solution 0.77% Administered Once Daily", were inspected in support of this application.

Drs. Torkildsen's and Rand's clinical sites were selected for inspection because of high subject enrollments and previous inspection histories.

II. RESULTS (by Site):

Name of CI, Location	**Protocol #/ Site #/ # of Subjects (enrolled)**	**Inspection Dates**	**Final Classification**
Gail Torkildsen, M.D. Andover Eye Associates 138 Haverhill Street Andover, MA 01810	C-10-126/ 3505/ 97	21-24 Oct 2014	NAI
Allison Rand, M.D. Rand Eye Institute 5 Sample Road Deerfield, FL 33064	C-12-028/ 6448/ 40	Nov 2014	Pending, preliminary classification NAI

Key to Classifications
NAI = No deviation from regulations.
VAI = Deviation(s) from regulations.
OAI = Significant deviations from regulations. Data unreliable.
Pending = Preliminary classification based on information in Form FDA 483 or preliminary communication with the field; EIR has not been received from the field or complete review of EIR is pending.

1. Gail Torkildsen, M.D.
   Andover Eye Associates
   138 Haverhill Street
   Andover, MA 01810

   a. What was inspected: At this site for Protocol C-10-126, 163 subjects were screened, 97 subjects were enrolled, and 94 subjects completed the study.

   The records for all subjects were reviewed which included but were not limited to informed consent forms for all screened subjects, financial disclosure forms, protocol adherence, subject eligibility, randomization, IRB communications, concomitant medications, adverse event reporting, and test article accountability and storage. Source data was compared with electronic case report forms (eCRFs) and verified against line listings.

   b. General observations/commentary: A Form FDA 483 was not issued at the conclusion of the inspection. Review of the records noted above revealed no significant discrepancies or regulatory violations.

   c. Assessment of data integrity: The study appears to have been conducted adequately, and the data generated by this site appear acceptable in support of the respective indication.

2. Allison Rand, M.D.
   Rand Eye Institute
   5 Sample Road
   Deerfield, FL 33064

   a. What was inspected: At this site for Protocol C-12-028, 41 subjects were screened, 40 subjects were enrolled in the study, and all 40 subjects completed the study.

   Informed consent forms were reviewed for all 41 screened subjects. Study data were validated for all 41 sets of records and the records of 20 subjects were reviewed for protocol compliance.

   b. General observations/commentary: A Form FDA 483 was not issued at the conclusion of the inspection Review of the records noted above revealed no significant discrepancies or regulatory violations.

   c. Assessment of data integrity: The study appears to have been conducted adequately, and the data generated by this site appear acceptable in support of the respective indication.

III. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

The clinical sites of Drs. Torkildsen and Rand were inspected in support of this NDA. Neither Dr. Torkildsen nor Dr. Rand was issued a Form FDA 483, and these inspections were classified No Action Indicated (NAI). The data generated by these clinical sites appear adequate in support of the respective indication.

NOTE: The final Establishment Inspection Report (EIR) for Dr. Rand's site has not been received by OSI. Should the classification of this inspection change upon review of the EIR, an inspection summary addendum will be issued to DTOP.

{See appended electronic signature page}

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CONCURRENCE: *{See appended electronic signature page}*

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