DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 5, 2013

Michael S. Sawaya
General Counsel
Altaire Pharmaceuticals, Inc.
311 West Lane
Aquebogue, NY 11839-0849

Dear Mr. Sawaya:

Your petition to the Food and Drug Administration requesting that FDA designate Gentak® Gentamicin Sulfate Ophthalmic Solution, eq. 0.3% base, Abbreviated New Drug Application ("ANDA") 064163, held by Akorn Inc., as an RLD for purposes of submitting an Abbreviated New Drug Application ("ANDA") for a generic version of this product, was received by this office on 06/05/2013. It was assigned docket number FDA-2013-P-0670/CP1, and it was filed on 06/05/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)