DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 24, 2013

Joan Janulis, R.A.C
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Dear Ms. Janulis:

Your petition to the Food and Drug Administration on behalf of Altaire Pharmaceuticals, Inc. requesting the FDA to designate AK-Fluor® 25% (fluorescein sodium) Injection, eq. 250 mg/ml, subject of NDA 022186, 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 04/24/2013. It was assigned docket number FDA-2013-P-0493/CP1, and it was filed on 04/24/2013. 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)