LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

April 23, 2013

VIA OVERNIGHT DELIVERY 4/23/13

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir or Madam:

On behalf of Altaire Pharmaceuticals, Inc. the undersigned submits this petition in quadruplicate under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 C.F.R. §§ 10.20 and 10.30, to request the Commissioner of the Food and Drug Administration to amend the Approved Drug Products with Therapeutics Equivalence Evaluations (commonly known as the "Orange Book") 33rd edition to designate AK-Fluor® 25% (fluorescein sodium) Injection, eq. 250 mg/mL (the "25% dosage strength"), New Drug Application ("NDA") 022186, held by Akorn Inc. as a reference listed drug (RLD). The product currently designated as the RLD is Fluorescite® (fluorescein sodium) Injection, eq. 100 mg/mL (the "10% dosage strength"), NDA 021980, which is held by Alcon Pharms. Ltd. However, there is presently no designated RLD for the 25% dosage strength of Fluorescein Sodium Injection listed in FDA's Orange Book.

A. Action Requested

By way of this petition, the undersigned requests the Commissioner of the Food and Drug Administration 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.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book," contains all FDA approved drug products. The FDA decided through the comment and rule-making process that it will designate all RLD products. The designated RLD selected by the Agency is the reference upon which an applicant relies in seeking approval of its ANDA. 57 Fed. Reg. 17,950, 17,954 (April 28, 1992). For multiple-source NDA drug products, the FDA decided to generally designate the market leader as the RLD. 57 Fed. Reg. at 17,958. However, the Agency recognizes for multiple-source products, a product not designated as the RLD and not shown to be bioequivalent to the RLD, may be shielded from direct generic competition. Therefore, if an applicant believes there are sound reasons for designating another drug product as the RLD, it should consult with FDA. 57 Fed. Reg. at 17,958.

There is a sound basis for designating AK-Fluor® (fluorescent sodium) 25% Injection as an RLD. The current edition of the electronic Orange Book (relevant pages provided as Attachment 1), identifies three NDAs for products containing fluorescent sodium - two active and one discontinued:

2013-2990

FDA-2013-P-0493

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NDA No.	Holder	Product Name/Route of Administration	Strength	Status
017869	Novartis	FUNDUSCEIN-25% (fluorescein sodium) Injection	250 mg/mL	Discontinued
021980	Alcon	FLUORESCITE® (fluorescein sodium) Injection	100 mg/mL	Active
022186	Akorn	AK-FLUOR® 10% (fluorescein sodium) Injection	100 mg/mL	Active
		AK-FLUOR® 25% (Fluorescein sodium) Injection	250 mg/mL	

Notably, Akorn's NDA filing was based on the Agency's earlier approval of Novartis' Funduscein-25%, NDA 017869 and Alcon's Fluorescite 10%, NDA 021980. (See Attachment 2, NDA 022186 Summary Review, p. 8.) However, the FDA only designated Alcon's Fluorescite® 10% drug product as the RLD with an "AP" therapeutic equivalence rating listed. Unless FDA designates Akorn's AK-Fluor® 25% drug product (NDA 022186) as an RLD, a generic applicant cannot submit an ANDA for that dosage strength of the product. This effectively shields AK-Fluor® 25% from generic competition, a consequence which strongly supports FDA designating the product as an RLD.

C. Environmental Impact

The petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

According to 21 C.F.R. § 10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information on which the petition relies, and that it includes representative data and information known to the petitioner, that are unfavorable to the petition.

Sincerely,

Joan Janulis, R.A.C.
Vice President

JJ/pk

Attachment 1: Approved Drug Products with Therapeutic Evaluations, Electronic Version, accessed April 23, 2013
Attachment 2: NDA 022186, AK-Fluor, 10% and 25% Summary Review

cc: Martin Shimer (Office of Generic Drugs)

Altaire Petition Fluorescein 042313