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June 4, 2013

VIA OVERNIGHT DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir or Madam,

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 Gentak® Gentamicin Sulfate Ophthalmic Solution, EQ 0.3% base, Abbreviated New Drug Application ("ANDA") 064163, held by Akorn Inc. as a reference listed drug (RLD). The product currently designated as the RLD is Gentamicin Sulfate Ophthalmic Solution, EQ 0.3% base, ANDA 064048, which is held by Bausch & Lomb. However, the formula for ANDA 064048 is not Q1Q2 equivalent to the formula for Gentak® ANDA 064163. Presently, there is no designated RLD for the product in a formulation Q1Q2 equivalent to the Gentak® ANDA 064163 listed in the 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 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.

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 Gentak® (Gentamicin Sulfate Ophthalmic Solution, EQ 0.3% base) as an RLD. The current edition of the electronic Orange Book (relevant pages provided as Attachment 1), identifies six active ANDAs for Gentamicin Sulfate Ophthalmic Solution, EQ 0.3% base:

ANDA No	Holder	Product Name/Route of Administration	Strength	Status
064163	Akorn	Gentak® Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active
062635	Akorn	Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active
0642452	Allergan	Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active
064048	Bausch & Lomb	Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active
0692196	Falcon	Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active
065121	Fera	Gentamicin Sulfate Ophthalmic Solution	EQ 0.3% base	Active

Notably, Akorn's ANDA filing was based on the Agency's earlier approval of Schering's NDA 050039 (also EQ 0.3% base). (See Attachment 2, ANDA 064163 Approval Letter, p. 1.) Schering's NDA 050039 was the first and originally approved formulation of the drug product. Subsequently Schering discontinued NDA 050039. (See Attachment 3, NDA 050039, Drugs at FDA listing.) NDA 050039 does not appear in the current Orange Book. (See Attachment 1 noted above.)

Presently, the Agency has only designated Bausch & Lomb's ANDA 064048 as the RLD. (See Attachment 4, Current Orange Book, ANDA 064048.) Altaire prefers to seek an ANDA approval for a formulation Q1Q2 equivalent to the original formulation NDA 050039, represented in the Orange Book presently by ANDA 064163. A Controlled Correspondence (CC# 13-0248) submitted by Altaire confirmed that our proposed formulation for Gentamicin Sulfate Ophthalmic Solution, eq. 0.3% base, is Q1Q2 equivalent to the Gentak® ANDA 064163, not the presently approved RLD ANDA 064048.

ANDA 064163 (Gentak® held by Akorn Inc.) is not listed as an RLD in the current Orange Book. (See Attachment 4, Current Orange Book, ANDA 06416.)

Unless FDA designates Akorn's Gentak drug product (NDA 064163) as an RLD, a generic applicant cannot submit an ANDA for a Q1Q2 equivalent to the originally approved formulation

NDA 050039. This effectively shields Gentak® from generic competition, a consequence which strongly supports FDA designating the product as an RLD.

C. Environmental Impact

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 know to the petitioner, that are unfavorable to the petition.

Sincerely,

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General Counsel

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Attachment 1: Current Orange Book 'Approved Drug Products with Therapeutic Equivalence Evaluations', Electronic Version, Accessed June 3, 2013

Attachment 2: ANDA 064163 October 12, 2001 Approval Letter, Electronic Version, Accessed June 3, 2013

Attachment 3: 'Drugs At FDA' NDA 050039, Electronic Version, Accessed June 3, 2013

Attachment 4: Current Orange Book 'Approved Drug Products with Therapeutic Equivalence Evaluations', ANDA 064048, Electronic Version, Accessed June 3, 2013

Attachment 5: Current Orange Book 'Approved Drug Products with Therapeutic Equivalence Evaluations', ANDA 064163, Electronic Version, Accessed June 3, 2013

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