DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

DEC 13 2013

Michael S. Sawaya
General Counsel
Altaire Pharmaceuticals, Inc.
P.O. Box 849
311 West Lane
Aquebogue, NY 11931

Re: Docket No. FDA-2013-P-0670

Dear Mr. Sawaya:

This letter responds to your citizen petition dated June 4, 2013 (Petition), requesting that the Food and Drug Administration (FDA or Agency) designate Gentak (gentamicin sulfate) ophthalmic solution, equivalent (EQ) 0.3% base, manufactured by Akorn Inc. (Akorn), under abbreviated new drug application (ANDA) 064163,[1] as an additional reference listed drug (RLD) in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[2]

We have carefully considered the Petition. For the reasons described below, your Petition is granted.

I. BACKGROUND

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the marketing of generic versions of a previously approved drug product when the generic drug product is the subject of an approved ANDA. To obtain approval, the ANDA sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product (1) has the same active ingredient(s) in the same strength, (2) has essentially identical labeling, and (3) is bioequivalent.

A *listed drug* is a new drug product that has an effective approval under section 505(c) of the FD&C Act for safety and effectiveness, or under section 505(j), that has not been withdrawn or suspended under section 505(e)(1) through (5) or (j)(5) of the FD&C Act and that has not been withdrawn from sale for reasons of safety or effectiveness.[3] Listed

[1] Please note that although the Petition refers to the referenced drug product by the trade name Gentak, the manufacturer has removed the trade name from the product's container and other labeling, which now describe the product as *Gentamicin Sulfate Ophthalmic Solution, USP.*

[2] The Orange Book is available on the Internet at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

[3] 21 CFR 314.3(b).

drugs are identified as drugs with an effective approval in FDA's Orange Book.[4] An *RLD* is the listed drug identified by FDA as the drug product on which an ANDA applicant relies in seeking approval of its application.[5]

Our policy on the designation of RLDs is stated in the preamble to the 1992 final rule establishing the requirements for ANDAs,[6] where in response to comments asking the Agency to explain how we determine which drugs should be RLDs, we stated:

> . . . FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data. FDA recognizes that, for multiple source products, a product not designated as the listed drug and not shown bioequivalent to the listed drug may be shielded from direct generic competition. If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA.[7]

II. DISCUSSION

In the Petition, you request that FDA designate Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base, manufactured by Akorn under ANDA 064163, as an additional RLD (Petition at 1). The Orange Book currently lists gentamicin sulfate ophthalmic solution, EQ 0.3% base, manufactured by Bausch & Lomb, Inc. (Bausch & Lomb) under ANDA 064048, as the RLD. Akorn's product, Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base, is currently listed as an approved product, but not an RLD.[8] You state that the two products are not Q1/Q2 equivalent.[9]

We have examined the issues presented in your Petition and have determined that you have stated grounds establishing that it is in the public interest to allow the submission of ANDAs that cite Akorn's Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base (ANDA 064163), as an additional reference standard. Akorn's Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% has been determined to be bioequivalent and therapeutically equivalent to Bausch & Lomb's gentamicin sulfate ophthalmic solution,

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[4] Id.

[5] Id.

[6] See *Abbreviated New Drug Application Regulations; Final Rule* 57 FR 17950, 17958 (April 28, 1992).

[7] Id.

[8] As a preliminary matter, we note that the RLD generally is a drug product approved under section 505(c) of the FD&C Act based on full reports of investigations of safety and effectiveness. We interpret your request to designate the Gentak ANDA as a second RLD to be a request to designate a therapeutically equivalent product as a reference standard for a proposed generic drug product.

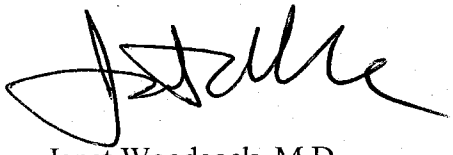
[9] Petition at 1. Products containing the same inactive ingredients in the same amounts are considered qualitatively (Q_1) and quantitatively (Q_2) identical. See, e.g., FDA's guidance for industry on *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* at 6-7 (available on the Internet at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm).

EQ 0.3% base, but the two drug products are not Q1/Q2 equivalent. Without a designation of Akorn's Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base, as an additional reference standard, an ANDA referencing this drug product may not be submitted, effectively shielding the drug product from generic competition. Therefore, in accordance with the policy stated in the 1992 final rule, we will designate Akorn's product, Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base, as an additional reference standard. An application submitted under section 505(j) may reference Akorn's Gentak (gentamicin sulfate) ophthalmic solution, EQ 0.3% base, provided that all other legal and regulatory requirements are met.

III. CONCLUSION

For the reasons described in this response, the Petition is granted.

Sincerely yours,



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