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

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November 15, 2013

VIA OVERNIGHT DELIVERY 11/15/13

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

Lachman Consultant Services, Inc. ("Lachman") is submitting this Citizen Petition in quadruplicate pursuant to 21 § C.F.R. 10.30 and in accordance with the regulations of 21 § C.F.R. 314.161, on behalf of a client, to request that the Commissioner of the Food and Drug Administration determine whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petition requests that the Commissioner of the Food and Drug Administration determine whether ZOVIRAX® (acyclovir sodium) for Injection, eq. 1 g base/vial (GlaxoSmithKline ("GSK")), NDA 18,603 has been voluntarily withdrawn from sale for safety or efficacy reasons.

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 (ANDAs). This list, referred to as the Orange Book, is divided into three sections: (1) approved prescription drug products; (2) approved over-the-counter drug products; and (3) discontinued drug products. ZOVIRAX® (acyclovir sodium) Injection eq. 1 g base/vial (GSK), NDA 18,603 was approved by the FDA on June 29, 1989. However, ZOVIRAX® (acyclovir sodium) for Injection, eq. 1 g base/vial is currently listed in the discontinued section of the Orange Book. A copy of the Orange Book's discontinued section listing ZOVIRAX® for Injection is provided as **Attachment 1**. The Petitioner is unaware of the precise date when ZOVIRAX® for Injection, eq. 1 g base/vial was removed from the approved prescription drug product section to the discontinued drug product section of the Orange Book. The Petitioner believes that GSK has discontinued marketing the drug product for commercial reasons.

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(1)).

As stated above, at the time of this petition's submission, there is no evidence that GSK is marketing ZOVIRAX® (acyclovir sodium) for Injection, eq. 1 g base/vial. Accordingly, Petitioner respectfully requests that FDA determine whether ZOVIRAX® (acyclovir sodium) for Injection, eq. 1 g base/vial was discontinued for reasons of safety or efficacy reasons, in order to enable action on an ANDA referring to ZOVIRAX® for Injection, eq. 1 g base/vial as the Reference Listed Drug. Should the NDA holder

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recommence marketing this strength of ZOVIRAX® for Injection after the submission of this petition and prior to an FDA response, and there is evidence that the product is available in the marketplace, the Petitioner will consider this petition moot. The Petitioner will at that time take the appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

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

Respectfully submitted,

Terri Nataline

Terri Nataline
Principal Associate

Attachment: Approved Drug Products with Therapeutic Equivalence Evaluations, Discontinued Drug Product Section, accessed November 14, 2013

cc: Martin Shimer (Office of Generic Drugs)

Petition Acyclovir 111513

From: (516) 683-1881 Origin ID: RMEA
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