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

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July 14, 2006

OVERNIGHT COURIER 7/14/06

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Phoslo (calcium acetate) Capsules eq 169 mg calcium have been voluntarily withdrawn from sale for safety or efficacy reasons.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, which are eligible for submission as abbreviated new drug applications (ANDAs). The list, referred to as the Orange Book, contains all FDA-approved drug products. Phoslo (calcium acetate) Capsules, eq. 169 mg calcium, NDA 21-160 was approved by FDA on April 2, 2001, 1990, and upon approval, considered to be "listed drug products" in the Orange Book. The product still appears in the Electronic Orange Book today in the Active Section, however, our client was advised by the FDA that the innovator, Nabi, has discontinued marketing the product.

Under FDA regulations drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

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As stated, the FDA has informed the applicant that the innovator has discontinued marketing of its Phoslo (calcium acetate) Capsules, eq. 169 mg calcium, under NDA 21-160. Therefore, because this drug product has been withdrawn from distribution, it is requested that the FDA determine whether the NDA holder's decision to discontinue marketing Phoslo (calcium acetate) Capsules was for reasons of safety or effectiveness.

Should the NDA holder recommence marketing of this product after the submission of this petition and prior to FDA response and there is evidence that the product is available in the marketplace, Lachman Consultant Services, Inc. will consider the petition moot. We will at that time take appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

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

E. Certification

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

Respectfully submitted,

Robert Pollock pk

Robert W. Pollock
Senior Vice President

RWP/pk

cc: Martin Shimer (Office of Generic Drugs)

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