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September 27, 2006

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate on behalf of a client, pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of FDA to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons, as outlined below.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 the Commissioner of FDA determine whether PhosLo® (calcium acetate) Tablets, eq 169 mg calcium, and PhosLo® (calcium acetate) Capsules, eq 169 mg calcium, have been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

FDA maintains a list of drug products which are eligible for submission as ANDAs. The list, referred to as the Orange Book, contains all FDA-approved drug products. PhosLo (calcium acetate) Tablets, eq 169 mg calcium, NDA No. 019-976, was approved by FDA on December 10, 1990, and upon approval, considered to be a "listed drug product" in the Orange Book. PhosLo (calcium acetate) Capsules, eq 169 mg calcium, NDA No. 021-160, was approved by FDA on April 2, 2001, and upon approval, considered to be a "listed drug product" in the Orange Book.

An "Active Ingredient" search on calcium acetate in the Electronic Orange Book indicates that the innovator, Nabi Biopharmaceutics, has discontinued the marketing of both PhosLo (calcium acetate) Tablets, eq 169 mg calcium, and PhosLo (calcium acetate) Capsules, eq 169 mg calcium, products.

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Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

Therefore, because these drug products have been withdrawn from distribution, as noted above, it is requested that FDA determine whether the NDA holder's decision to discontinue the marketing of PhosLo (calcium acetate) Tablets and Capsules was for reasons of safety or effectiveness.

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

C. Environmental Impact

A claim for a categorical exclusion of an environmental assessment report, based upon 21 CFR 25.31, is hereby made.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

E. Certification

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

Sincerely,

Miguel A. de Soto-Perera, Ph.D.
Vice President, Pharmaceutical Sciences
Beckloff Associates, Inc.