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

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

October 29, 2003

OVERNIGHT DOCUMENT 10/29/03

Division of Dockets Management
Food and Drug Administration (HFA-305)
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 10.25(a) and 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.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 Pyridostigmine Bromide Tablets, 30 mg for the treatment of myasthenia gravis (ANDA 89-572 held by Solvay) have been voluntarily withdrawn from sale for safety or efficacy reasons.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 that are eligible for submission as abbreviated new drug applications (ANDAs). The List (Approved Drug Products with Therapeutic Equivalence Evaluations), referred to as the Orange Book, contains all FDA-approved drug products. Pyridostigmine Bromide Tablets, 30 mg was approved by the FDA on November 27, 1990 (ANDA 89-572) and currently appears as a "listed drug product" in the "Discontinued Section" of the most current update to the electronic Orange Book (accessed October 29, 2003).

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations at 21 CFR 314.161 also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

Because the drug product referred to in this petition appears in the discontinued section of the Orange Book, it is requested that the FDA determine whether Solvay's decision to discontinue

the marketing of its Pyridostigmine Bromide Tablets, 30 mg under ANDA 89-572 was for reasons of safety or effectiveness.

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 that are unfavorable to the petition.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Vice President

RWP/pk

cc: Cecelia Parise (Office of Generic Drugs)

B05P3302