



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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April 2, 2004

Ms. Marilyn A. Friedly
PharmaForce, Inc.
1507 Chambers Road
Columbus, Ohio 43212

Re: Docket No. 2003P-0393/CP1

Dear Ms. Friedly:

This letter responds to your citizen petition submitted on August 25, 2003, requesting that the Food and Drug Administration (FDA) determine whether Diazepam Injection USP, 5 mg/mL, 1-mL (ANDA No. 72-079), by Abbott Laboratories, was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that Diazepam Injection USP, 5 mg/mL, 1-mL was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain Diazepam Injection USP, 5 mg/mL, 1-mL in the *Discontinued Drug Product List of Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 443-5540.

Sincerely,

Elizabeth Sadove
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

03P-0393

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