



# PharmaForce, Inc.

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August 25, 2003

Dockets Management Branch  
Food and Drug Administration (HFA-305)  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

## CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations of 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons, as outlined below.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whether Diazepam Injection USP, 5 mg/mL, 1-mL, (ANDA No. 72-079), by Abbott Laboratories Inc., has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

### B. Statement of Grounds

The publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List / Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

The current edition of the "Electronic Orange Book" (*Approved Drug Products with Therapeutic Equivalence Evaluations*) lists Diazepam Injection USP, 5 mg/mL, 1-mL, (ANDA No. 72-079), by Abbott Laboratories Inc., in the Drug Product List section ("Active").

As of the date of this submission, Diazepam Injection USP, 5 mg/mL, 1-mL, (ANDA No. 72-079), by Abbott Laboratories Inc., is not available in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the Food and Drug Administration determine whether Abbott's decision not to market Diazepam Injection USP, 5 mg/mL, 1-mL, was for reasons of safety or effectiveness.

2003P-0393

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CP1

August 25, 2003  
Page 2 of 2

**C. Environmental Impact**

A claim for categorical exclusion of the requirements for 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 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 petitioner relies, and that includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,



Marilyn A. Friedly  
Director  
Regulatory Affairs