PharmaForce, Inc.

November 28, 2001

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 I0.30 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Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for **safety** or effectiveness reasons, as outlined below.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 Rubramin PC@ (Cyanocobalamin Injection USP) 1 mg/mL, 10-mL, (NDA No. 06-799), by Bristol Myers Squibb, has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons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of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

Please note, the current edition of the "Electronic Orange Book" (*Approved Drug Products with Therapeutic Equivalence Evaluations)* lists Rubramin PC@ (Cyanocobalamin Injection USP) 1 mg/mL, Product 004 (1 mL), (NDA No. 06-799), by Bristol Myers Squibb, in the Drug Product List section. Although not currently marketed, the drug product was also available in a 10-mL multidose configuration, as evidenced by its inclusion in the 1983 Physician's Desk Reference (see attached). The 10-mL configuration is not fisted in either the Drug Product List or Discontinued Drug Product List sections of the Orange Book.

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OIP-0533 CPI

As of the date of this submission, Rubramin PC@ (Cyanocobalamin Injection USP) 1 mg/mL, 10-mL, (NDA No. 06-799), by Bristol Myers Squibb, 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 Bristol Myers Squibb's decision not to market Rubramin PC@ (Cyanocobalamin Injection USP) 1 mg/mL, 10-mL, was for reasons of safety or effectiveness.

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 petition 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