

HFA-305



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 29 2002

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Food and Drug Administration
Rockville MD 20857

Marilyn A. Friedly
Director, Regulatory Affairs
PharmaForce, Inc.
1507 Chambers Road
Columbus, Ohio 43212

Docket No. 01P-0533/CP1

Dear Ms. Friedly:

This letter responds to your citizen petition dated November 28, 2001, requesting that the Food and Drug Administration (FDA) determine whether Rubramin PC (Cyanocobalamin Injection) 1 mg/mL, 10 mL has been withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janet Woodcock".

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0533

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