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Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

1546 '03 APR -2 P1:22

March 28, 2003

RE: Docket # 02P-0435 (Citizen Petition)

Dear Sirs:

As a physician treating people with hemophilia and von Willebrand disease, I am requesting on behalf of my patients your agency's prompt approval of Alphanate in the management of von Willebrand Disease.

My patients participated in the prospective study of Alphanate's efficacy in the management of patients with von Willebrand disease and I can attest, first hand, to the efficacy of the product in their clinical care. Until the study there had only been case reports and small retrospective series of patients with VWD unresponsive to Desmopressin treated with plasma concentrates.

See: "Treatment of Von Willebrand Disease with a High-Purity Factor VIII/Von Willebrand Factor Concentrate: A Prospective, Multicenter Study" by Mannucci et al published on Blood (2002:Vol 99 #2).

The pending approval of Alphanate for the treatment of Von Willebrand Disease will provide my patients an important supply option in case of shortages. As recent supply problems have illustrated it is not in my patient's interest to have only one supplier of needed therapy. Imagine if Humate-P were to be in short supply and I had to manage my patients with cryoprecipitate!

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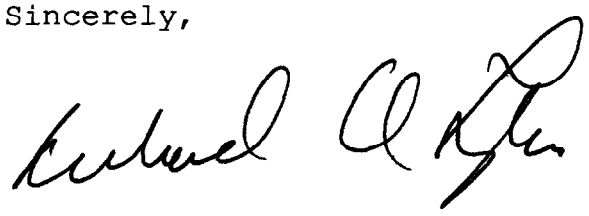
On behalf of my patients, I earnestly hope that your agency will promptly approve Alphanate's use in the management of von Willebrand disease.

Sincerely,



Richard A Lipton, MD, MPH, FACP
Physician in Charge
Comprehensive Hemophilia Center

cc: Dr. Jesse Goodman
Director, Center for Biologics Evaluation and Research
NIH Building 29B, Room #5
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