University of Colorado Health Sciences Center

Mountain States Regional Hemophilia and Thrombosis Center
Colorado State Treatment Program
School of Medicine

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

April 3, 2003

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

To Whom It May Concern:

This letter serves the purpose of requesting that the FDA approve a new label indication for Alphanate® for the management of von Willebrand disease. As a physician treating over 450 persons with bleeding disorders including von Willebrand disease, I want to ensure that my patients have access to more than one product for treatment of their disorder.

Alpha Therapeutic Corporation was the only company to conduct a prospective study to assess the efficacy of a FVIII/vWF concentrate in vWD patients for whom desmopressin was either ineffective or contraindicated (Manucci et al, *Blood* 2002:Vol 99 #2). Prior to this all studies had been retrospective.

Over the past two years, a significant problem in supply of clotting factor products has demonstrated that there must be more than one manufacturer and their products available for each bleeding disorder. At present, Aventis Behring's Humate-P® is the only drug indicated for von Willebrand Disease and if this product were to fall into shortage, our patients would be at risk.

Please consider this request and the importance that having an additional product -- Alphanate® manufactured by Alpha Therapeutics--with an indication for treatment of von Willebrand disease available.

Sincerely,

Marilyn Manco-Johnson, MD
Professor, Pediatric Hematology/Oncology
University of Colorado Health Sciences Center
Director, Mountain States Regional Hemophilia & Thrombosis Center

Cc: Dr Jesse Goodman
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