



**NATIONAL HEMOPHILIA FOUNDATION**

*for all bleeding disorders*

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Chief Executive Officer

January 28, 2003

ATTN: Dockets Management Branch  
U.S. Food and Drug Administration  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857

**Re: Docket Number 02P-1435 (Citizen Petition)**

Dear Sirs:

Enclosed find the comments of the National Hemophilia Foundation to Rear Admiral Marlene E. Haffner, MD, MPH, director, Office of Orphan Products Development, with regard to the orphan drug application filed by Alpha Therapeutic Corporation seeking approval of Alphanate® for treatment of von Willebrand disease (vWD).

Please contact my office if you have any questions about the letter.

Sincerely,

Richard T. Hellner  
Chief Executive Officer

02P-0435

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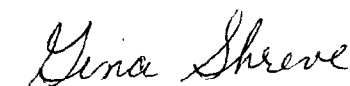
**Marlene E. Haffner, MD, MPH**  
Rear Admiral, U.S. Public Health Service  
Director, Office of Orphan Products Development  
U.S. Food and Drug Administration  
5600 Fishers Lane, Room 15A-08  
Rockville, MD 20857

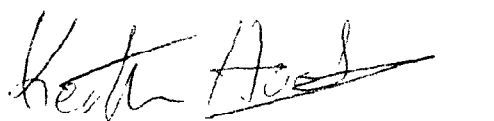
Dear Dr. Haffner:

We are writing to express support for the orphan drug application filed by Alpha Therapeutic Corporation seeking approval of Alphanate® for treatment of von Willebrand disease (vWD), an inherited bleeding disorder. Approximately one to two percent of all individuals in the United States are affected by vWD. Despite outreach efforts, most of these individuals remain undiagnosed, with women being more likely than men to be diagnosed because of their monthly bleeding cycle. As treatment options for vWD are limited, approval of Alphanate® for this indication would increase treatment options for women who do not respond well to currently approved treatments as well as safeguard against potential shortages of treatment therapies.

We encourage your careful review and urge your approval of Alpha Therapeutic Corporation's application for use of Alphanate® in the treatment of vWD.

Sincerely,

  
Gina Shreve, Ph.D.  
President

  
Keith Hoots, M.D.  
Chairman, Medical and Scientific  
Advisory Committee