
Office of Orphan Products Development(HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Internet website: <http://www.fda.gov/orphan>

April 14, 1999

Centeon LLC
1020 First Avenue
King of Prussia, PA 19406-1310

Attention: Carol S. Marchione
Associate Director, Regulatory Affairs

Dear Ms. Marchione:

Reference is made to the orphan product Humate-P® (antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized), sponsored by Centeon Pharma GmbH, which was designated an orphan product pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 360bb) on October 16, 1992 (application #92-679) for the treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.

This letter is to inform you that as the first sponsor of Humate-P® to obtain marketing approval for this indication, you are entitled to seven years of exclusive marketing approval pursuant to Section 527 of the FFDCA (21 U.S.C. § 360cc) for the use of Humate-P® (1) in adult patients for treatment and prevention of bleeding in hemophilia A (classic hemophilia) and (2) in adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate. The exclusive seven year approval period began on April 1, 1999, the date of approval of your biological license application (BLA 96-1099).

Please note that holders of exclusivity for approved orphan products are required to assure the availability of sufficient quantities of an orphan product to meet the needs of patients. Failure to do so could result in the withdrawal of the product's exclusive approval [21 CFR 316.36(b)].

Thank you for your efforts in developing Humate-P® for the treatment of hemophilia A and von Willebrand disease. The whole premise of the Orphan Drug Act and program is based on the realization that the resources and commitment devoted to the development of products for "orphan" populations may not provide financial returns to their sponsors. It is with genuine gratitude that we recognize your efforts.

Sincerely yours,



Marlene E. Haffner, MD, MPH
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development