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PETITION FOR STAY

On behalf of Aventis Behring L.L.C. (Aventis Behring or Petitioner), the undersigned submits this petition under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs (Commissioner) stay effective approval of Alphanate® for treatment of von Willebrand disease (vWD) until the agency has responded to Aventis Behring's October 2, 2002 Citizen Petition. In its Citizen Petition, Aventis Behring requests that the Commissioner refrain from granting effective approval of Alphanate® for the treatment of von Willebrand Disease (vWD) until the expiration of orphan drug exclusivity for Humate-P® on March 31, 2006.

A. Actions Requested

Aventis Behring requests that the Commissioner stay effective approval of Alphanate® for treatment of vWD pending final resolution of the issues in Aventis Behring's October 2, 2002 Citizen Petition. The need for dispatch in this case is particularly acute because, upon information and belief, approval of Alphanate® for treatment of vWD may be imminent.

B. Statement of Grounds

Under 21 C.F.R. § 10.35(e), FDA must grant a stay of action if all of the following criteria are satisfied:

- (1) the petitioner will otherwise suffer irreparable injury;
- (2) the petitioner's case is not frivolous and is being pursued in good faith;
- (3) the petitioner has demonstrated sound public policy grounds supporting the stay;
and

OAP- 0435

PSA 1

KLEINFELD, KAPLAN AND BECKER

- (4) the delay resulting from the stay is not outweighed by public health or other public interests.

As demonstrated below, all of these criteria are met here.

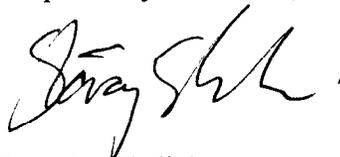
Without a stay, Aventis Behring will suffer irreparable injury. Aventis Behring invested significant resources in developing Humate-P® for an orphan population with the reasonable expectation of seven years of exclusivity should the product be the first approved for this indication, which it was. If Alphanate® is approved for the same indication, Aventis Behring will lose market share and there is no mechanism by which market share lost to a competitor can be recovered. Like the loss to the plaintiffs in Bracco Diagnostics, Inc. v. Shalala, the loss to Aventis Behring in the absence of a stay, “[w]hile ... ‘admittedly economic,’” would be without “‘adequate compensatory or other corrective relief’ that can be provided at a later date, tipping the balance in favor of [the] ... relief.” Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 29 (D.D.C. 1997) (citation omitted).

As its Citizen Petition demonstrates, Aventis Behring’s case is not frivolous and is being pursued in good faith. Further, sound public policy grounds support the stay. Congress enacted the Orphan Drug Amendments (the “Amendments”) in 1983 to, among other things, encourage industry to perform the research and development of drugs for the treatment of rare diseases that affect a small patient population. If Alphanate is approved for the same indication as Humate-P, it will not only vitiate Aventis Behring’s orphan drug exclusivity in this case but also will undermine this critical objective of the Amendments. Moreover, “[t]he public’s interest in ‘the faithful application of the laws’ outweigh[s] its interest in immediate access to [a competing] product.” Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998). This is particularly true where, as here, Aventis Behring has more than adequate supply to meet the demands of the orphan population impacted by the disease state in question, von Willebrand Disease.

C. Conclusion

For the reasons set forth above, the undersigned submit that the Commissioner should stay effective approval of Alphanate® for treatment of vWD until the agency has responded to Aventis Behring’s October 2, 2002 Citizen Petition.

Respectfully submitted,



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Counsel for Aventis Behring L.L.C.

SLE/s