DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

MAR - 7 2003

Stacy L. Ehrlich, Esq.
Counsel for Aventis Behring L.L.C.
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D. C. 20036-6606

Re: Docket Number 02P-0435/CP1

Dear Ms. Ehrlich:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet completed its response to the issues raised in your citizen petition and petition for stay of action submitted on October 2, 2002, on behalf of Aventis Behring L.L.C. In your citizen petition, you request that FDA refrain from granting effective approval of Alphanate Antihemophilic Factor (Human) for the treatment of von Willebrand Disease until the expiration of orphan drug exclusivity for Humate-P Antihemophilic Factor/von Willebrand Complex (Human) on March 31, 2006.

We are still considering your requests and supporting information stated in your citizen petition and petition for stay. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petitions as soon as we have reached a decision on your requests.

Sincerely yours,

Jesse L. Goodman, M.D., M.P.H.
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Branch
(HFA-305)

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