June 8, 2020

George M. Stone, Jr.
Patients for Access to Advanced Therapy for Hemophilia
114 Cloak Ln
Lake Frederick, VA 22630

Re: Citizen Petition [Docket No. FDA-2019-P-6099]

Dear Mr. Stone:

I am writing to you regarding the above-referenced citizen petition filed on behalf of Patients for Access to Advanced Therapy for Hemophilia (PAATH) and the cosigners of the citizen petition received by the Dockets Management Staff on December 30, 2019. In your petition, you request that the Commissioner of Food and Drugs (the Commissioner) pursue enforcement action, if the Food and Drug Administration (FDA) has not already done so, against Bayer U.S., as a subsidiary of Bayer AG, that "will prevent the reoccurrence of its mislabeling nearly 1,000 vials of hemophilia A treatment Kogenate FS; improper storage of hemophilia treatment products; and release of expired hemophilia treatment products to the U.S. consumer market."

I am writing to inform you that the FDA has not yet reached resolution of the issues raised in your citizen petition due to the existence of other FDA priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov