DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 31, 2019

George M. Stone, Jr.
Patients for Access to Advanced Therapy for Hemophilia
(b) (6)
[redacted]

Sent via email to: accessadvancedtherapy@gmail.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to pursue enforcement action, if the FDA has not already done so against Bayer U.S., as 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 US consumer market was received by this office on 12/30/2019.

It was assigned docket number FDA-2019-P-6099. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.12.31 14:12:02 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)