April 16, 2020

Stephen Hahn, M.D
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002 via regulations.gov

RE: Status of Actions in Response to Citizen Petition FDA-2019-P-6099-0001

Dear Dr. Hahn,

Patients for Access to Advanced Therapy for Hemophilia (PAATH) filed a Citizen Petition on December 30, 2019 concerning enforcement actions against Bayer U.S., a subsidiary of Bayer AG. A copy of our petition is enclosed.

In July 2019, Bayer issued a voluntary recall of Kogenate® FS Antihemophilic Factor (Recombinant) 2,000 IU because they were mislabeled. The vials contained a different Bayer hemophilia product, Jivi® antihemophilic factor (Recombinant) PEGylated-aucl 3,000 IU. Kogenate® FS is approved to treat or control bleeding in adults and children with hemophilia A. Jivi® is approved to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. The Jivi® batch expired as of August 2018. This is significant in that the wrong medication could have been administered to a patient, and there is a potential risk that the patient could develop an inhibitor to FVIII as a result.

We are writing you concerning the overall status of our petition and the FDA's response. To begin, the FDA did not properly acknowledged receipt of our petition.[1] Perhaps this was a clerical error. Nonetheless, the FDA initiated its 180-day comment period.

It has now been over 90-days since we filed our petition. We believe this should be more than adequate time for the FDA to review and respond to the matters we raised along with our proposed actions. At a minimum, the FDA should be able to provide us with an interim update. We would hope that the hemophilia community does not have to wait for the comment period to end (or even beyond that time) as that would be well over a year since the incident at issue occurred.

[1] We received an acknowledgement on December 31, 2019 but it is to Donovan Rosling Rosling for a variance application for a Laser Light Show. See attached.

Accordingly, we request a corrected acknowledgement of filing of our Citizen Petition and an update regarding actions taken to address the concerns we raised. We request a response by April 30, 2020.

Sincerely,

George M. Stone, Jr., patient and advocate
On behalf of: Patients for Access to Advanced Therapy for Hemophilia (PAATH) and below listed cosigners
114 Cloak Ln, Lake Frederick, VA 22630
Phone: 703-815-6069
Email: accessadvancedtherapy@gmail.com

Cosigners:
Mark Antell, patient, advocate, Past Vice President, Hemophilia Federation of America; Past Principal in People with Bleeding Disorders and HCV

Ray Dattoli, patient, advocate, Past Vice President, Committee of Ten Thousand

Stephen Long, patient and advocate

Rich Vogel, patient, advocate, Past President, Hemophilia Federation of America; Past President Hemophilia Association of New Jersey

Patients for Access to Advanced Therapy for Hemophilia

Citizen Petition
Date: December 30, 2019

Patients for Access to Advanced Therapy for Hemophilia (PAATH) and cosigners submit this petition under 21 USC Part 352 (Misbranded drugs and devices) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to pursue enforcement action if the FDA has not already done so against Bayer U.S., as subsidiary of Bayer AG.

A. Action Requested
Petitioners request the Commissioner to seek enforcement actions, such as one or more administrative orders or consent agreements, against Bayer U.S., 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.

In addition, we recommend that the FDA assess whether other factor producers have sufficient safeguards to ensure they will not experience similar events.

B. Statement of Grounds
On July 19, 2019 Bayer issued a voluntary recall (copy attached) of two lots of Kogenate® FS Antihemophilic Factor (Recombinant) 2000 IU vials in the US. Certain vials from these two lots that were labeled as Kogenate® FS actually contain the FVIII hemophilia A treatment, Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. The affected lots were distributed from February 5, 2019 to July 15, 2019 from Bayer's distribution sites in Berkeley, CA and Shawnee, KS. Bayer stated that it had alerted the FDA and was working closely with it to manage the recall.

Kogenate® FS is approved to treat or control bleeding in adults and children with hemophilia A. Jivi® is approved to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. The Jivi® batch expired as of August 2018. This is significant in that the wrong medication could have been administered to a patient, and there is a potential risk that the patient could develop an inhibitor to FVIII as a result.

As patients and advocates for the bleeding disorders community, and as survivors of the contaminated blood supply and blood products of the 1970's and 80's, we are deeply concerned about the quality control failures. We are alarmed that Bayer released more than 900 vials of clotting factor treatment that were not only actually a different product but were also expired.

Why are we so concerned? We are alarmed because Bayer has a history of ethical failure to the hemophilia community. This is not the first time that Bayer has made a profit from selling dangerous product to people with Hemophilia. In the 1980's when Bayer's Cutter Laboratories realized that their Factor VIII and IX products were contaminated with HIV, the financial investment in the product was considered too high to destroy the inventory. Rather, Cutter

misrepresented the results of its own research and sold the contaminated Factor to overseas markets without the precaution of heat treatment recommended for reducing the risk. As a consequence, patients who infused the HIV-contaminated Factor VIII and IX were infected with HIV, developed AIDS. This was a widely publicized incident, which caused one nationally syndicated TV columnist (Joe Scarborough on MSNBC) to label Bayer, "Rat of the Week." See: https://www.youtube.com/watch?v=spnEaO3yumk. For a detailed discussion of this incident see the Wikipedia article, 'Contaminated Haemophilia Blood Products.'

Only a small fraction of those affected by viral contamination of Factor still remain. We remember and honor our brothers, now mostly gone, who often said, "All I want from Bayer is a cure ... and my friends back."

Hemophilia patients depend on safe product to live well. We, patients and trusted supporters, should not give a free pass to anyone, or to any corporation, that endangers product safety. The mislabeling of expired Factor VIII warrants appropriate and strong enforcement action on the part of the FDA.

C. Environmental Impact
This petition and action requested is categorically excluded under (A) Claim for categorical exclusion under 21 CFR §25.31.

D. Economic Impact
To be submitted, if requested by the Commissioner.

E. Certification
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(b) (6) [redacted]

Signed: George M. Stone, Jr., patient and advocate
On behalf of: Patients for Access to Advanced Therapy for Hemophilia (PAATH) and below listed cosigners

(b) (6) [redacted]

Email: accessadvancedtherapy@gmail.com

Cosigners:
Mark Antell, patient, advocate, Past Vice President, Hemophilia Federation of America; Past Principal in People with Bleeding Disorders and HCV

Ray Dattoli, patient, advocate, Past Vice President, Committee of Ten Thousand

Stephen Long, patient and advocate

Chad Blair, patient and advocate

Rich Vogel, patient, advocate, Past President, Hemophilia Federation of America; Past President Hemophilia Association of New Jersey

Dana Brayshaw, President, Hemophilia Association of the Capital Area (HACA) Board of Directors and the following additional HACA Board members:
- Robin Monin, Vice President
- Callie Victor, Secretary
- Sandesh Mohan, Treasurer
- Melissa Alba
- Artura Jackson
- April Owens
- Jennifer Sleboda
- Michelle Stielper
- Patrick Kanu

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

December 31, 2019

Donovan Rosling Rosling
(b) (6) [redacted]

Sent via email to: (b) (6) [redacted]

Dear Petitioner:

Your petition to the Food and Drug Administration to approve a variance application for a Laser Light Show was received by this office on 12/30/2019.

Your request for a Variance was assigned docket number FDA-2019-V-6101. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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

cc: X-Laser (variances@x-laser.com)