

Joint Statement on Recall of Bayer Kogenate® FS Lots

July 26, 2019

Last week, Bayer announced the recall of two lots of Kogenate® FS antihemophilic factor (recombinant) 2000 IU vials. That highly concerning announcement has raised many questions on the part of both national organizations and community members.

The fact that one product (Jivi), past its expiration date, was mislabeled as another product (Kogenate FS) and distributed to the public for six months is an event that should never have happened. Today, HFA and NHF have submitted a letter to Bayer focusing on the company's plans for accomplishing the recall, asking specifically:

- How will Bayer notify patients of the recall,
- Where is all the recalled product now,
- How will the product be destroyed, and
- How will Bayer communicate with the hemophilia community and with the FDA about this process.

This is only the first step in what we expect to be continuing communications with Bayer and the FDA about how this serious event happened and how Bayer will ensure similar errors do not happen again. Our priority today was to communicate to Bayer the need to expeditiously and thoroughly communicate to every patient impacted by this recall and learn more about Bayer's plan to execute this recall.

This is an ongoing discussion and HFA and NHF will keep the bleeding disorders community informed as information is gathered.

Please note that NHF and HFA do not recommend, endorse or make any representation about the efficacy, appropriateness or suitability of any specific products, treatments, or opinions. Please consult your physician before use of any treatments.