HFA and NHF are pleased to share a brief update with the community concerning a recent meeting we had with the FDA as well as a number of additional resources that the FDA provided after the call. On September 25th , HFA and NHF had a teleconference with a large team from FDA's Center for Biologics Evaluation and Research, including Center Director Dr. Peter Marks. During the meeting, HFA and NHF shared the concerns of the bleeding disorders community regarding Bayer's distribution and subsequent recall of mislabeled, expired factor. The FDA personnel explained that they are limited in how much they can disclose about an active investigation, but they attentively listened to our concerns, and provided general information about FDA processes, including how they investigate reports of adverse events reported to the agency. The FDA was also able to share that the agency has classified the Bayer recall as a class 2 recall (see more information from the FDA here, and an article with details about the classification of recalls may be found here).

Here are some of the resources the FDA identified, containing additional information about FDA processes:

- Information about the FDA's MedWatch adverse event reporting system can be found here: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program. The FDA also maintains a page called "How Consumers Can Report an Adverse Event or Serious Problem to FDA:" https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda.
- FDA inspections information can be found in the agency's online classification database: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-classification-database. Users can scroll down the page to the link for "Inspection Classification Database Search" to search by firm name, or go to the "Project Area" and scroll down to CBER Project 42 – Blood and Blood Products.
- FDA enforcement reports are listed here: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports.

HFA and NHF will continue to update the bleeding disorders community as any further information develops.

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. If you have any questions or concerns about your medical treatment, including your possible exposure to recalled product, please consult your physician.