FDA DRUG RECALLS

A recall is an action taken by a manufacturer to remove a product from market.

Recalls Can Be Issued By:

VOLUNTARY

Almost all recalls are begun as voluntary

- Initiated by manufacturer
- Manufacturer is responsible for contacting users about recall

FDA REQUESTED

Urgent

- Initiated by FDA due to potential harm
- Based on agency determination that action is needed to potect public health and welfare

FDA MANDATED

Very limited

- Narrowly restricted by federal statute
- FDA can only order recall if it fits within statute limitation
- FDA may issue public warning

VOLUNTARY & FDA REQUESTED RECALLS ARE CONSIDERED **MANUFACTURER INITIATED**

All recalls are initiated with a written order citing violation, product, lot and serial numbers and timeline for recall.

HFA
Hemophilia Federation of America™