

CSL Behring
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IMPORTANT: VOLUNTARY DRUG RECALL EXTENSION
Helixate® FS

August 10, 2016

Dear Helixate® FS Customer,

This letter is a follow-up to the communication sent to you on July 21, 2016 regarding a voluntary recall of two lots of hemophilia A drug Helixate® FS containing active ingredient manufactured before November 2015. The lots communicated on July 21, 2016 are:

Product	Lot Number	NDC Number	Expiry Date
HELIXATE FS 2000 IU	270R979	0053-8134-02	09/17/2017
HELIXATE FS 2000 IU	270TN1G	0053-8134-02	06/06/2018

An analysis was conducted of additional lots with active ingredient manufactured before November 2015 to determine if there was a need for further action. The analysis is now complete and, as a result, we are voluntarily recalling additional lots.

Routine stability testing showed potency is declining faster than expected in these lots, which is why the recall is being conducted. The material is packaged in 5mL glass vials and comes in a shelf carton with Sterile Water for Injection, USP, filter transfer set and package insert.

In two lots, potency levels fell below the pre-specified acceptable range. These two lots are:

Product	Lot Number	NDC Number	Expiry Date
HELIXATE FS 2000 IU	270PWG6	0053-8134-02	05/08/2017
HELIXATE FS 1000 IU	270NV9G	0053-8133-02	09/23/2016

For additional lots, potency may eventually fall below the pre-specified acceptable range before shelf life expiry. These lots are listed in a table on page two ("Additional Lots Subject to Recall").

It is important to note that based on all currently available and reviewed data that no safety observations or signals have been detected by drug safety and the current health risk assessment does not indicate an appreciable risk for patients for the affected lots.

CSL Behring is initiating a retail level voluntary recall*. As such, we ask that you please:

- Immediately quarantine inventory of the affected product under your direct control
- If applicable, immediately contact your retail (pharmacy) level customers to have the identified product removed from pharmacy inventories
- Complete the attached Returned Goods Form and follow the instructions to arrange for return of the identified product from your current inventory and, if applicable, returns coming from your retail level customer base to the referenced CSL Behring address.

CSL Behring is committed to minimizing any potential disruption in product supply. If you have questions related to replenishment, please call your wholesaler or CSL Behring Customer Service at 1-800-683-1288 or customersupport@cslbehring.com. For other inquiries, please call me at 610-878-4586.

Sincerely,

CSL Behring Biotherapies for Life
Quality Assurance Manager

* Retail level recall: product recall to the level immediately preceding the consumer or patient level; includes retail and hospital pharmacies.

Additional Lots Subject to Recall:

Product	Lot Number	NDC Number	Expiry Date
HELIXATE FS 250 IU	270P892	0053-8131-02	09/15/2016
HELIXATE FS 250 IU	270PH46	0053-8131-02	11/18/2016
HELIXATE FS 250 IU	270P4NL	0053-8131-02	11/22/2016
HELIXATE FS 250 IU	270R5CH	0053-8131-02	05/29/2017
HELIXATE FS 250 IU	270R0LV	0053-8131-02	05/29/2017
HELIXATE FS 250 IU	270R7N5	0053-8131-02	08/13/2017
HELIXATE FS 250 IU	270RV8T	0053-8131-02	12/19/2017
HELIXATE FS 250 IU	270TGX1	0053-8131-02	02/07/2018
HELIXATE FS 500 IU	270NTPP	0053-8132-02	09/08/2016
HELIXATE FS 500 IU	270P8V6	0053-8132-02	11/07/2016
HELIXATE FS 500 IU	270R5K1	0053-8132-02	08/11/2017
HELIXATE FS 500 IU	270RR6J	0053-8132-02	08/27/2017
HELIXATE FS 500 IU	270RHG3	0053-8132-02	11/23/2017
HELIXATE FS 500 IU	270RTPX	0053-8132-02	12/15/2017
HELIXATE FS 500 IU	270T2T8	0053-8132-02	01/29/2018
HELIXATE FS 1000 IU	270P9CR	0053-8133-02	01/09/2017
HELIXATE FS 1000 IU	270RV9C	0053-8133-02	12/21/2017
HELIXATE FS 1000 IU	270T0R4	0053-8133-02	01/08/2018
HELIXATE FS 1000 IU	270T508	0053-8133-02	02/18/2018
HELIXATE FS 1000 IU	270TW0V	0053-8133-02	07/08/2018
HELIXATE FS 1000 IU	270V5P1	0053-8133-02	07/08/2018
HELIXATE FS 2000 IU	270NW81	0053-8134-02	10/02/2016
HELIXATE FS 2000 IU	270PCPX	0053-8134-02	02/09/2017
HELIXATE FS 2000 IU	270PP8N	0053-8134-02	02/09/2017
HELIXATE FS 2000 IU	270R0NN	0053-8134-02	06/12/2017
HELIXATE FS 2000 IU	270R53J	0053-8134-02	07/31/2017
HELIXATE FS 2000 IU	270R9HV	0053-8134-02	09/26/2017
HELIXATE FS 2000 IU	270RR1G	0053-8134-02	12/07/2017
HELIXATE FS 2000 IU	270T556	0053-8134-02	03/03/2018
HELIXATE FS 3000 IU	270NPV1	0053-8135-02	08/15/2016
HELIXATE FS 3000 IU	270NT1J	0053-8135-02	08/27/2016
HELIXATE FS 3000 IU	270PJ1G	0053-8135-02	03/05/2017
HELIXATE FS 3000 IU	270PP5C	0053-8135-02	04/10/2017
HELIXATE FS 3000 IU	270R83W	0053-8135-02	09/06/2017
HELIXATE FS 3000 IU	270RXCT	0053-8135-02	12/30/2017
HELIXATE FS 3000 IU	270T4G4	0053-8135-02	02/13/2018
HELIXATE FS 3000 IU	270TG53	0053-8135-02	03/27/2018
HELIXATE FS 3000 IU	270TGWJA	0053-8135-02	04/09/2018
HELIXATE FS 3000 IU	270TGWJ	0053-8135-02	04/09/2018
HELIXATE FS 3000 IU	270TTR7	0053-8135-02	06/22/2018