



NATIONAL HEMOPHILIA FOUNDATION

for all bleeding and clotting disorders

Medical Advisory #415

November 16, 2011

Baxter Announces Labeling Error on Sterile Water

Baxter Healthcare Corporation has sent a notice of a labeling error affecting the expiration date of the Sterile Water for Injection that is packaged as a diluent with RECOMBINATE [Antihemophilic Factor (Recombinant)]. The Sterile Water for Injection label indicates that the shelf life is longer than what was actually approved by the FDA.

Please continue to use the RECOMBINATE product as labeled on the kit. There is no impact to the safety or efficacy of Recombinate if the Sterile Water for Injection diluent is used before the expiration date of the RECOMBINATE.

The following are the NDC and Lot numbers of the Sterile Water for Injection vials:

| NDC Number | Lot Number | Size | Expiration Date |
|------------|------------|-------|-----------------|
| 0944284210 | TRA11802AC | 10 mL | 01-23-2014 |
| 0944284410 | TRA11810AC | 10 mL | 03-22-2014 |
| 0944284410 | TRA11803AC | 10 mL | 01-25-2014 |
| 0944284410 | TRA11803AD | 10 mL | 01-25-2014 |

| | | | |
|------------|------------|-------|------------|
| 0944284410 | TRA11810AA | 10 mL | 03-22-2014 |
| 0944284510 | TRA11805AA | 10 mL | 02-01-2014 |
| 0944284510 | TRA11805AB | 10 mL | 02-01-2014 |
| 0944284510 | TRA11805AC | 10 mL | 02-01-2014 |
| 0944284510 | TRA11819AA | 10 mL | 06-20-2014 |
| 0944284310 | TRA11808AC | 10 mL | 02-23-2014 |
| 0944284310 | TRA11816AA | 10 mL | 05-18-2014 |
| 0944284310 | TRB11820AA | 10 mL | 07-14-2014 |
| 0944284310 | TRA11806AC | 10 mL | 02-07-2014 |

If you have any questions, please call Stericycle, Inc. at 1-888-UPDATE-U.

PHYSICIANS: Please distribute this information to all providers in your area who treat patients with hemophilia.

CHAPTERS: Please distribute this information to your membership.

Please sign up for the Patient Notification System (PNS) to be notified directly about the latest recall or withdrawal of recombinant and plasma products. The system is confidential and time sensitive. It is administered by an independent third-party organization and is free of charge. To enroll in the PNS, please go online at <http://www.patientnotificationsystem.org/> or else call (888) UPDATE-U.

This material is provided for your general information only. NHF does not give medical advice or engage in the practice of medicine. NHF under no circumstances recommends treatment for specific individuals and in all cases recommends that you consult your physician or local hemophilia treatment center before pursuing any course of treatment.