Important New Drug Warning

March 29, 2002

Dear Doctor/Healthcare Provider:

This letter is to advise you of a change in the labeling to add an important new warning for certain patients receiving **PLAS+® SD** (Pooled Plasma, (Human) Solvent Detergent Treated). The boxed warning, which appears in the beginning of the Product Circular, reads as follows:

PLAS+® SD SHOULD NOT BE USED IN PATIENTS UNDERGOING LIVER TRANSPLANT OR IN PATIENTS WITH SEVERE LIVER DISEASE AND KNOWN COAGULOPATHIES

In October 2000, a Dear Doctor letter was issued regarding reports of serious adverse events occurring in a cluster of six patients, who underwent orthotopic liver transplantation for end stage liver disease due to a variety of underlying disease processes. The six patients, who died due to thrombotic events or excessive bleeding during the transplant procedure, received intra-operative **PLAS+® SD** along with multiple other blood components. Following the occurrence of these serious adverse events, there have been additional reports of deaths due to thromboembolic complications or severe bleeding in patients with severe liver disease with known coagulopathies or in patients undergoing liver transplant.

Subsequent to the October 2000 letter, an evaluation of all available information on the reported serious adverse events was performed and has resulted in a strengthened warning. Also added to the Warnings is a note of caution to carefully monitor the coagulation status of patients receiving large volumes of **PLAS+® SD** for evidence of thrombosis, excessive bleeding or exacerbation of disseminated intravascular coagulation (DIC). Additionally, information regarding spontaneous reports of thrombotic events in patients with acute TTP undergoing plasma exchange following infusion of **PLAS+® SD** has been added to the Adverse Reactions section of the revised Product Circular.

Healthcare professionals should report adverse events associated with or possibly associated with the use of **PLAS+® SD** to INFOTRAC® at 1-800-535-5053. Alternatively, this information may be reported to FDA's MedWatch Reporting System by phone (1-800-FDA-1088), fax (1-800-FDA-0178), via the MedWatch website at www.fda.gov/medwatch, or by mail (using postage paid form) to MedWatch, HF-2, 5600 Fisher's Lane, Rockville, MD 20852-9787. Health professionals and consumers should use the Form 3500 for adverse event reporting.

Please refer to the amended full prescribing information.

Sincerely,

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PLAS+® SD is distributed by the American National Red Cross, Blood Services
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