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July 15, 2010

**WinRho SDF Product Information**

Dear Customer,

Cangene is experiencing a temporary shortage of liquid WinRho<sup>®</sup> SDF 1500 IU (300 µg) and liquid WinRho<sup>®</sup> SDF 600 IU (120 µg) vials due to a temporary manufacturing interruption with respect to these vial sizes.

The freeze dried WinRho<sup>®</sup> SDF 1500 IU (300 µg) and WinRho<sup>®</sup> SDF 600 IU (120 µg) product will replace the liquid formulation in the inventory during this interruption. All freeze dried formulated product will be as suitable as the previous liquid formulated material.

WinRho freeze dried product has been licensed in Canada since 1980 for the Rh prophylaxis indication and treatment of Rh incompatible blood transfusions. In 1996, WinRho SDF also received licensure for the treatment of immune thrombocytopenic purpura (ITP). In November 2007 Cangene received approval by Health Canada for the liquid formulation and introduced that product to the Canadian market in June 2008.

A significant component for licensure of the liquid formulation was quality studies and data bridging the previous freeze dried product presentation to the current liquid WinRho SDF presentation. Bioequivalence was demonstrated between the two formulations for the IV route of administration in study WS-029. A subsequent study was performed, WS-038, in which bioequivalence of the two formulations was demonstrated for the IM route of administration. Both bioequivalence studies demonstrated that the liquid and freeze dried formulations of WinRho have a comparable pharmacokinetic profile.

It is anticipated that the WinRho SDF liquid formulation will be available in the near future and we regret any inconvenience this may cause in the clinical setting.

Should you have any questions regarding this information please contact Cangene's bilingual customer service department at 1-877-CANGENE (226-4363) or my office at 416-675-8290 or email: [customerservice@cangene.com](mailto:customerservice@cangene.com).

Sincerely,  
CANGENE CORPORATION



David Young, National Sales Manager  
WinRho/HepaGam B