

February 3, 2012

Reference No.: STKH12002

Dear PPTA Stakeholders,

PPTA is pleased to announce that, as of today, reporting of data on the U.S. supply of certain plasma protein therapies has resumed.

To be precise, the information posted on the Association's Web site this morning consists of U.S. distribution data for five products – Immune Globulin, Albumin 5%, Albumin 25%, Recombinant Factor VIII, and Plasma-Derived Factor VIII – for the month of October 2011. Going forward, updated information on the same group of products will be posted on PPTA's Web site at the beginning of each month with an equivalent, 3-month reporting lag (e.g., data for November 2011 will be reported at the beginning of March, data for December 2011 will be reported at the beginning of April, etc.).

As explained in a November 2011 Letter to Stakeholders,¹ PPTA has not implemented the 3-month reporting lag lightly or without due consideration for its potential impact on the shortage preparedness utility of this vital, public health-related information. Indeed, we believe the change has strengthened the data program including, most notably, by ensuring maximum participation by the manufacturers of plasma protein therapies that supply the U.S. market.

In a recent Food & Drug Administration (“FDA”) report on drug shortages, the Center for Biologics Evaluation & Research (“CBER”) – the FDA sub-unit with regulatory responsibility for the plasma protein therapies industry – gave an extremely favorable assessment of industry participation in shortage preparedness initiatives. Specifically, CBER noted that industry provides “[g]ood cooperation and early notification [of potential shortages]”² By constantly working to strengthen and improve its North America data program, including through the changes implemented today, PPTA hopes to continue this record of success.

If you have any questions regarding the changes, or would like to discuss further, please do not hesitate to contact Association staff.

Sincerely,



Julie A. Birkofer
Senior Vice President
PPTA North America

¹ PPTA Letter to Stakeholders re: North America Data Program (Nov. 15, 2011) *available at* <http://www.pptaglobal.org/news/news.aspx?nid=96>.

² U.S. Dep't of Health and Human Servs. and FDA, *A Review of FDA's Approach to Medical Product Shortages* 25, 43 (Oct. 31, 2011) *available at* <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm277755.pdf>.

PPTA - Plasma Derived Factor VIII

Monthly U.S. Distribution and 12 Month Rolling Average Distribution

