Plasma Protein Therapeutics Association

December 17, 2004
Reference No.: FDAA04024 **VIA E-MAIL**

Jay S. Epstein, M.D., Director
Office of Blood Research and Review
Food and Drug Administration
1401 Rockville Pike, (HFM-300)
Rockville, MD20852

Dear Dr. Epstein:

On behalf of its member companies, the Plasma Protein Therapeutics Association (PPTA) commends you for taking action to eliminate the need to track, in plasma donors, a 10-lb. weight loss over a two-month period. The Center's current thinking was expressed at the PPTA/FDA liaison meeting on September 10, 2004, and the Blood Products Advisory Committee (BPAC) meeting on October 22, 2004. Based on those presentations, we have some outstanding questions and request clarification of details in your current thinking.

It was our understanding of the discussions from the September PPTA/FDA liaison meeting that the expectation for industry was that there would be a mechanism to detect unexplained, chronic weight loss in donors. However, in the Agency presentation at the October BPAC meeting, the stated recommendation was that "tracking of 10-lb weight loss [is] to be performed at the time of the annual physical." We understood from the liaison meeting that the expectation is that an individual donor's weight over time will be reviewed to detect unexplained weight loss. The continued use of the 10-lb measurement has even less relevance annualized than it may have had over a two-month period of time. It would be helpful if the Center's expectations, including parameters of the annual review and whether there are product implications when a chronic, unexplained weight loss is noted in the absence of indicators such as history or test results, could be clarified. Also, does the Agency plan to issue a draft guidance document to outline these expectations? The industry would be willing to work with FDA to develop a cogent process.

At the liaison meeting, it was also expressed that changes to standard operating procedures (SOPs) to eliminate the two-month tracking could be submitted in an annual report [per 21 CFR 601.12(d)]. The reporting mechanism was not mentioned at the BPAC meeting. We are requesting confirmation that notification in an annual report is the appropriate reporting mechanism. Additionally, what guidance has been given to field investigators?

The Center's presentation at the October BPAC meeting recommended that "donor informational materials [be] harmonized with those in place for whole blood donor eligibility." PPTA continues to work with the AABB Interorganizational Task Force on

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

the donor history questionnaire. PPTA's proposal for the uniform donor history questionnaire includes donor information in a high risk poster. Although a different format than the AABB's approved materials, the high-risk poster possesses content concerning unexplained weight loss that is the same. While we know of no plasma centers using the self-administered donor questionnaire, we would like to identify an area that may cause difficulty with the apparent expectation that donors with unexplained weight loss should be deferred. The July 3, 2003, guidance document entitled, "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires," contains in the Introduction (Section I) the following: "[This guidance] also supersedes Section I.A of FDA's memorandum dated April 23, 1992, entitled 'Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products.'" Section I.A of the referenced blood memorandum contains the recommendation to include information concerning unexplained weight loss.

Thank you for your willingness to modify outdated and obsolete recommendations. If you have questions or want to discuss, please feel free to contact me. We appreciate your time in clarifying these matters and look forward to your response.

Sincerely,

Mary Gustafson
Senior Director, Global Regulatory Policy
Plasma Protein Therapeutics Association