DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

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Mary Gustafson
Senior Director, Global Regulatory Policy
Plasma Protein Therapeutics Association
140 Old Solomons Island Road, Suite 100
Annapolis, MD 21401

Dear Ms. Gustafson:

This letter is in response to your letter dated December 17, 2004 in regard to questions/clarifications you have concerning elimination of the need to track, in plasma donors, a 10-lb. weight loss over a two-month time period.

Discussions from the September PPTA/FDA liason meeting outlined that there should be a mechanism in place to detect unexplained weight loss in donors. Agency presentation at the October 21-22, 2004 BPAC meeting states "tracking of 10-lb weight loss can be performed at the time of the annual physical." In your letter to us you question the need for tracking weight loss and state "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." CBER recognized that tracking 10-lb weight losses in donors over a two-month period of time is considered a cumbersome process by Source Plasma establishments and is an outdated and ineffective procedure to reduce risk from HIV in plasma products. However, unexplained weight loss is still considered a general indicator of a disease process and since Source Plasma donors are weighed each time they come into the center to donate, the weight-loss data is readily available and should be reviewed by medical personnel. This can be done at the time of annual physical. It can also be performed more frequently, if center personnel thinks that would prove more relevant.

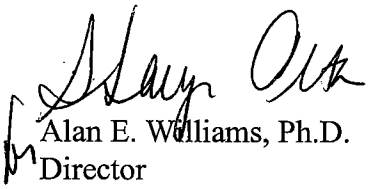
The Compliance Program Policy Manual - Inspection of Source Plasma Establishments was revised on December 1, 2004, and attachment B pertaining to Donor Eligibility has taken out reference to tracking 10-lb weight loss over a 2-month time period and now states "The Source Plasma establishment should provide AIDS educational material, including information about high-risk activities, to donors at each visit. The Source Plasma establishment should have and follow its SOPs pertaining to any unexplained donor weight loss." This Compliance Program Policy Manual is distributed to all field offices.

Changes to standard operating procedures (SOPs) to eliminate the two-month tracking can be submitted in an annual report.

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 1) the following: "[This guidance] also supercedes Section 1.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 1.A of the referenced blood memorandum contains the recommendation to include information concerning unexplained weight loss. However, it is not the content of the educational documents that is being superseded. Rather, it is the direct questioning that is being superseded as the new guidance is about self-administered questioning. Your comment will be noted and forwarded to the committee working on the self-administered questionnaire guidance document to determine if further clarification is needed.

Should you have any questions, please contact Linda M. Alms at 301-827-3543 or by FAX 301-827-3534.

Sincerely yours,



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