Update Summary
Blood Products Advisory Committee
October 21-22, 2004

Topic: **FDA's current thinking regarding data tracking by Source Plasma establishments to identify a 10-lb donor weight loss in a 2 month period**

Background:

Tracking donors to permit identification of a 10-lb weight loss in a two month period commenced following CBER's revised memorandum "Revised Recommendations to Decrease the Risk of Transmitting Acquired Immunodeficiency Syndrome (AIDS) from Blood and Plasma Donors" dated 12/14/84. These recommendations, issued prior to the development of laboratory tests for markers of HIV infection described interim procedures to minimize the risk of transmitting AIDS through blood products or plasma derivatives. These procedures included specific donor questions concerning unexpected weight loss as a criterion of donor suitability. In addition, as stated in the memorandum, "The existing cumulative records of each source plasma donor's weight should be examined to assure that any weight loss of 10 pounds or more in less than two months is detected."

The 12/14/84 memorandum was superseded by a memorandum dated 2/5/90, entitled "Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products," which also included the recommendation to defer donors on the basis of an unexplained weight loss of 10 lbs in a two month period. An addendum to this memorandum, Section I B, Additional Procedure for Source Plasma, states "The existing cumulative records of each Source Plasma donor's weight should be examined on the day of collection to assure that any weight loss of 10 pounds or more in less than two months is detected."

A subsequent 4/23/92 memorandum entitled, "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products" addressed the additional possibility of HIV-2 exposure, but no longer made mention of the 10-lb weight loss tracking obligation for Source Plasma donors. The memorandum did not specifically state whether the 2/5/90 memorandum was to be superseded.

The current "Guide to Inspections of Source Plasma Establishments" revised April 2001 still requires (Section II, Page 11, Item 6, Weight) that the "Source Plasma donor's weight should be examined to assure that any weight loss of 10 pounds or more in less than two months is detected."

Discussion:

Since the early 1980's, sensitive tests for HIV antibodies, improved testing technology, and licensed NAT for HIV-1 have reduced or eliminated the predictive value of weight loss tracking. FDA's current thinking is that unexplained weight loss remains a general indicator of possible ill health, but does not add a margin of safety with respect to HIV/AIDS.

All whole blood and Source Plasma collection establishments currently list unexplained weight loss as a sign or symptom of HIV/AIDS in donor informational materials, In addition, this information is presented to each Source Plasma donor in the form of a High-Risk Poster at which time the donor is questioned as to whether he/she has any of the signs or symptoms listed.

Source Plasma donors are weighed at each donation in order to determine how much plasma to obtain. These weights are recorded in the plasma donor's records and are available for review as deemed appropriate by the center's medical staff. Current practice includes active review of weight records for the previous two months to rule out unexplained weight loss. Industry has expressed concern that this active process is out of date and burdensome in the current Source Plasma collection environment.

Current requirements pertinent to Source Plasma donor eligibility include: *21 CFR 640.63, Suitability of donor, (a), "The suitability of a donor for Source Plasma shall be determined by a qualified licensed physician or by persons under his supervisions and trained in determining donor suitability. Such determination shall be made on the day of collection from the donor by means of a medical history, tests, and such physical examination as appears necessary to the qualified licensed physician." And, as per 21 CFR 640.63 (b) (1) "Each donor shall be examined by a qualified licensed physician on the day of the first donation or no more than 1 week before the first donation and at subsequent intervals of no longer than 1 year."*

FDA's Current Thinking:

FDA's current thinking is that our recommendation for active review of weight records to determine a 10-lb weight loss among Source Plasma donors can be satisfied by a review of such records at the time of the annual physical examination. Additionally, we believe that other donor informational materials should be harmonized with those in place for whole blood donor eligibility (i.e. that the donor information should contain wording analogous to the "FDA-accepted" Uniform Donor History Questionnaire in regard to unexplained weight loss.)

References:

1) December 14, 1984 FDA Guidance "Revised Recommendations to Decrease the Risk of Transmitting Acquired Immunodeficiency Syndrome (AIDS) from Blood and Plasma Donors"

2) February 1990 FDA Guidance "Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products"

3) April 23, 1992 FDA Guidance "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products"

4) FDA Guide to Inspections of Source Plasma Establishments, June 1997 (April 2001 – Editorial Revisions)