30 Years of Leadership
ABRA

The International Authority for the Source Plasma Collection Industry

147 Old Solomons Island Rd. • Annapolis, MD • USA • 21401
Tel: 410.263.8296 • Fax: 410.263.2298
www.plasmainfo.org

November 14, 2001
Reference No. FDAA01 014

VIA HAND DELIVERY

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (August 2001)," Docket No. 01 D-0220

Dear Sir or Madam:

ABRA is pleased to provide these comments on the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (August 2001)." ABRA is the trade association and standards-setting organization for the Source Plasma collection industry. ABRA represents the interests of approximately 400 plasma collection centers nationwide. These centers are responsible for the collection of nearly 11 million liters of Source Plasma annually. This plasma makes up roughly 60% of the world's plasma supply and is manufactured into life-supporting and life-sustaining therapies.

The Source Plasma industry recognizes the importance of Biological Product Deviation Reports (BPDR) and appreciates the Agency's assistance in defining the types of reports and the timeframe for reporting. Industry is requesting clarification on the submission of BPDRs for donors that subsequently test positive for viral markers and deferrals resulting from new donor history questions.

Section IV.A.(1) [page Ii'] of the Draft Guidance includes the following language for describing unforeseen or unexpected events:

> "Other similar situations that would be reportable as an unforeseen or unexpected event that may affect the safety, purity or potency of previously distributed

> products include:. . . Donor tested negative and products were distributed, the donor returns and subsequently tested positive for any viral marker."

Given the baseline prevalence of the viruses tested in the population, the situation referenced above, in which a donor with a negative history subsequently tests positive for a viral marker, is not considered to be an "unexpected" or unforeseeable" event. Industry currently uses safety nets such as donor screening, the viral marker standard, PCR testing and inventory hold to reduce the potential risk associated with this type of event. Procedures, such as "lookback" in which units are retrieved and destroyed, protect public health. Therefore, industry is requesting that FDA re-consider the requirement for the submission of BPDRs for this type of event and consider an alternative data collection mechanism. Industry would be pleased to meet with FDA to discuss an alternate mechanism.

Industry is also requesting clarification on the BPDR requirements for the addition of a new question to the donor history questionnaire as part of the donor screening process. The Draft Guidance entitled, "Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products (August 29, 2001)" recommends that Source Plasma centers include additional travel questions during the screening process- The guidance language implies that BPDRs will be required for donors that become deferred as a result of the new donor screening questions. This reporting mechanism is not an efficient means for reporting the impact of new screening questions. Industry is interested in meeting with FDA to discuss an alternate mechanism for the collection of these data.

ABRA appreciates the opportunity to comment on this Draft Guidance. Should you have any questions regarding these comments or would like additional information, please contact me. Thank you for your consideration.

Respectfully submitted,

Trish Landry

Trish Landry
Director, Regulatory Affairs