



**The International Authority for the
Source Plasma Collection Industry**

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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SUBJECT: Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD) by Blood and Blood Products (August 2001)," Docket No. 97D-0318

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ABRA is pleased to provide these comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD) by Blood and Blood Products (August 2001)," Docket No. 97D-0318. 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 Plasma Collection Industry recognizes that this guidance document addresses complex issues having complex solutions. Industry is also aware of the potential effects that donor deferrals and product retrievals may have on the supply of these important blood and plasma therapies. As such, Industry plans to monitor the plasma supply and continue dialogue with the Agency as the final guidance recommendations are implemented.

Given the complex nature of the document, it is challenging for the reader to properly classify the donor and determine the appropriate actions for donor deferral, product retrieval, and reporting. Industry is requesting the addition of a table to the document to aid the reader in determining the appropriate donor

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classification and show the specific course of action that is required for each classification.

Several of the following points could also be clarified in the table:

1. Recommendations for product retrieval and quarantine for donors with vCJD are listed in both Section V.A. and Section V.C. FDA notification is required in Section V.C.; however, Section V.A. does not state that FDA notification is required. The reporting requirements should be more clearly stated.
2. Section V.C. states that FDA notification is required as soon as possible. Industry is requesting clarification as to whether a Biological Product Deviation Report (BPDR) suffices as notification to FDA or if in addition to the BPDR, Industry is required to notify the FDA via telephone or official written correspondence. Prior guidance documents had required that the blood establishment report these cases both to FDA and CDC, and Industry requests clarification as to whether CDC should be notified as well.
3. Donors with a "physician's clinical or pathological diagnosis of CJD and age less than 55 years" is mentioned in Section V.C. and Section V.D.3. This category of donor should be clearly harmonized with the category specified as "Clinical diagnosis of "suspected" vCJD."
4. Section V.C. discusses the recommendations for product retrieval and quarantine for blood and blood components, including Source and Recovered Plasma, from donors with vCJD or "suspected" vCJD. The disposition of unpooled source plasma, intermediates, and final products prepared from Source Plasma that had been collected from donors considered to have a "Clinical diagnosis of "suspected" vCJD" is not clearly specified.
5. Section IV.D. states three different requirements for asking the recommended donor screening questions: Once, annually, and intervals not to exceed three months. These different intervals should be clarified relative to the donor classification.

As stated above, the Draft Guidance recommended that Source Plasma centers should include additional donor screening questions. Section IV.D. states that



the proposed questions 4 and 5 should be asked of Source Plasma donors at an interval of no greater than three months. Industry recognizes the need for assessing current risk, however, the interval at which Source Plasma donors are asked Question 4 should be revised to "no greater than four months" as part of the donor screening questions at the time of the four-month sampling. The Source Plasma centers are currently tracking Serum Protein Electrophoresis (SPE) for the donors at four-month intervals. In addition, Question 5 should be asked at the annual physical, and updated throughout the year as part of one of the current screening questions. Revising the intervals at which these questions are asked would be less cumbersome for the centers and adherence to the guidance would most likely be improved.

Section IV.A. of the document states that Source Plasma establishments should "appropriately counsel" donors at an increased risk for CJD. Industry is requesting clarification on the expectation for appropriate counseling of donors for CJD and vCJD.

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
Director, Regulatory Affairs