AMERICAN
ASSOCIATION
OF BLOOD BANKS

October 10, 2001

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

Re: Docket No.97D-0318 — Draft Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products

Dear Docket Officer:

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

The AABB appreciates the opportunity to comment on this "Draft Guidance for Industry, Revised Preventive Measures to Reduce the Possible risk of Transmission of Creutzfeldt-Jakob Diseases (CJD) and Variant Creutzfeldt –Jakob Disease (vCJD) by Blood and Blood Products." We especially appreciate the explicit statements concerning the need to consider both the safety and availability of the blood supply. The proposed phased-in approach should be helpful in attempting to balance these two concerns. The AABB also appreciates the extensive background information discussion of CJD and vCJD as it relates to the FDA's rationale for blood donor deferral. It clearly explains how the FDA has arrived at these decisions.

We support continued monitoring of scientific information on CJD, vCJD, BSE and other TSEs, as well as the availability of blood for patient needs. Policy must continue to be reevaluated and revised as quickly as possible whenever new information is available.

Additional specific comments will be submitted directly from the AABB interorganizational task forces, the Circular of Information for the Use of Blood and Blood Components (Circular), and the Uniform Donor History Questionnaire (UDHQ). The Circular task force has representatives from AABB, America's Blood Centers (ABC), and liaisons from the FDA, and will comment on the labeling provisions of the guidance. The UDHQ task force also includes the American Blood Resources

97D-0318 C 26

8101 Glenbrook Road ♦ Bethesda, MD 20814-2749 ♦ Phone: (301) 907-6977 ♦ Fax: (301) 907-6895
Web site: www.aabb.org ♦ Email: aabb@aabb.org

Association (ABRA), the Armed Services Blood Program Office (ASBPO), representatives of other disciplines, and liaisons from the Centers for Disease Control and Prevention (CDC0, and will comment on the proposed donor questions.

In addition to the abovementioned comments, the AABB has the following specific comments:

Section IV A 2, Recommended Donor Deferral Criteria, requires "you should indefinitely defer and appropriately counsel donors....." **The AABB requests that "appropriately counsel" should be deleted.** That language does not appear in any of the other described deferrals in Section A. Further, on June 11, 2001 the FDA issued a final rule "General Requirements for Blood, Blood Components, and Blood Derivatives: Donor Notification." This draft guidance appears to add additional requirements not stated in the final rule. Section 630.6(b)(4) of the rule states, "Where appropriate, information about medical follow-up and counseling." While many blood centers do voluntarily provide or refer donors to counseling, "appropriate counseling" should not be a requirement.

The AABB recommends that the language in section V B be revised to read **"You should immediately retrieve and quarantine for subsequent destruction, all in-date blood components, except for Source Plasma *and recovered plasma* under your control (including Whole Blood, blood components, and Source Leukocytes.)**

Section V B discusses retrieval and quarantine for Blood and Blood Components Intended for Transfusion or Further Manufacture from Donors with Five or More Years Residence in Europe. While in-date Source Plasma is exempted from quarantine and subsequent destruction, recovered plasma is not. This appears to contradict earlier statements in the guidance. Section IV C states that, "Consistent with this recommendation, recovered plasma collected prior to deferral from donors with 5 years or more travel or residence in Europe is still considered acceptable for manufacturing of plasma derivatives." In section IV C, the stated reason for permitting Source Plasma donations is "the likely ability of plasma fractionation processes to reduce TSE infectivity, and the uncertain effects of a deferral upon the supply of plasma." Recovered plasma would be subjected to these same plasma fractionation processes and should not be required to be quarantined and destroyed. Further, the stated reasons for deferring further donations for recovered plasma is to prevent inappropriate use of blood and blood components for transfusion. We agree with prohibiting further donations, but any recovered plasma that has already been collected should not be required to be retrieved.

The term Whole Blood Donor should be replaced with a broader definition to clarify that blood and blood components collected by apheresis and intended for transfusion are included. Numerous places in the draft guidance refer to "Whole Blood and Source Plasma Donors." We believe that the term Whole Blood Donor is intended to incorporate not only Whole Blood, but also any blood component that is intended for transfusion purposes. However, not all blood components intended for transfusion are prepared from Whole Blood. We believe that the FDA intends to include components

collected by apheresis, such as plateletpheresis, red cells by apheresis, and plasmapheresis if it is intended for transfusion purposes. A different definition is needed to make this clear.

The AABB appreciates the opportunity to comment on this draft guidance. Any questions may be directed to Kay Gregory, Director Regulatory Affairs, at 910-842-2790 or kayg@aabb.org.

Sincerely,

Karen Shoos Lipton, JD
Chief Executive Officer