
**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

May 8, 2001
Reference No. FDAA01008

VIA FAX

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

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans (February 2001)," Docket No. 00D-1662

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ABRA is pleased to provide these comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans (February 2001, Docket No. 00D-1662). 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.

ABRA agrees that recipients of xenotransplantation products are unacceptable as plasma donors or donors of allogeneic blood and tissue. Currently, FDA has measures in place to assure that xenotransplantation donors do not become plasma or blood donors. Xenotransplantation takes place only under FDA-approved clinical protocols that must include recipient counseling. This counseling involves notifying trial participants that they must never donate blood or plasma. The clinical protocols also address that household members of xenotransplantation recipients are also advised of the risks of zoonoses and presumably counseled regarding not donating blood or plasma.

In addition, ABRA agrees that the addition of screening questions to the blood donor history questionnaire to detect xenotransplant product recipients is unnecessary. The current donor screening questions are likely to exclude such donors. Plasma centers, like whole blood centers, routinely ask donors if they

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are under a doctor's care, taking any medication, had any recent surgeries, or have ever received a tissue or organ transplant. These questions, in addition to the physical exam performed, are likely to result in the deferral of xenotransplant recipients and their household members.

Due to the concern about the complexity of the donor history screening questionnaire, and the lack of validation for most of its questions, the AABB has spearheaded a task force to streamline the donor history questionnaire. ABRA participates on this task force, in addition to representatives from America's Blood Centers, American Red Cross, liaisons from the CDC, and FDA. This task force has reviewed the proposed xenotransplant questions to be asked of blood donors and agreed that the public will most likely not understand the proposed questions. Requiring the institutions and programs that initiate and support xenotransplantation would be a more effective means to notify the individuals at risk that they must not donate plasma, blood or tissue, rather than posing these questions to all blood and plasma donors.

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
Manager, Regulatory Affairs

TLL

30 Years of Leadership
ABRA

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