AMERICAN
ASSOCIATION
OF BLOOD BANKS

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May 16, 2001

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

Docket No OOD-1662

Dear Docket Officer:

The American Association of Blood Banks recently submitted comments to Docket No OOD-1662, Draft "Guidance for Industry: Source Animal, Product, Preclinical and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans.

I have just discovered a typographical error in the body of the comments. The comments submitted by the AABB, reference Section VII J in two separate places. The correct reference should be Section VIII J.

Attached are revised comments with the correct reference. There are no other changes to the comments.

Yours truly

Kay Gregory

Kay Gregory
Director Regulatory Affairs

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

OOD-1662

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AMERICAN
ASSOCIATION
OF BLOOD BANKS

May 7, 2001

Dockets Management Branch (HFA-305) **(CORRECTED MAY 16, 2001)**
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket No OOD-1662 Draft "Guidance for Industry: Source Animal Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans;" Availability

The American Association of Blood Banks (AABB) appreciates this opportunity to comment on the Draft Guidance for Industry Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans. 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 is particularly interested in issues relating to blood donation deferral as discussed in Section VIII J. Informed Consent. Requirements for Participation in the Study, Section 2 a ii states that *"as an interim precautionary measure, xenotransplantation product recipients and certain of their contacts should be deferred indefinitely from donation of whole blood, blood components, including source plasma and source leukocytes, tissues, breast milk, ova, sperm, or any other body parts for use in humans. Pending further clarification, contacts to be deferred from donations should include persons who have engaged repeatedly in activities that could result in intimate exchange of body fluids with a xenotransplantation product recipients."*

The AABB agrees that recipients of xenotransplantation products are unacceptable as donors of allogeneic blood and tissue. Parenthetically, because of donor restrictions regarding medication use and general health, virtually no xenotransplant product recipient would qualify as a blood donor. **The AABB also suggests that the requirement to refrain from donating blood or tissue should be included in the informed consent for the recipient of a xenotransplant product.** We believe that the transplant programs have the responsibility to transmit this information as part of the

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

consent process. **The AABB also suggests that patients who have received xenotransplant products in the past and did not receive such information should be located and informed.**

Section VIII J 2 a i states that *"the patient should consent to inform his current and future contacts of their potential risks from the source animal species and of their deferral from blood donation."* The definition of contacts has been improved as the guidance now defines contacts to be deferred from donation as *"persons who have engaged repeatedly in activities that could result in intimate exchange of body fluids with a xenotransplantation product recipient. For example, such contacts may include sexual partners, household members who share razors or toothbrushes, and health-care workers or laboratory personnel with repeatedpercutaneous mucosal or other direct exposures."*

The AABB is concerned about the requirement to defer as blood and tissue donors certain contacts of xenotransplant product recipients. Deferral for contact with xenotransplant recipients is unsupported by any evidence of transmission of potential or unrecognized pathogens to such contacts after xenotransplantation. A major concern regarding transmission of zoonotic pathogens to xenotransplant recipients is that the immunosuppression required to permit rejection will render them uniquely susceptible to infection. Immunosuppression is not an issue in the contacts. The risk to such contacts is amenable to study in populations with occupational exposure to the relevant species, but to date, we are not required to defer farmers, abattoir workers, veterinarians or others with potential zoonotic contact. If the agency decides to defer certain contacts, then this policy should also be emphasized in the informed consent for the patient.

Addition of questions to the blood donor history questionnaire to detect xenotransplant product recipients and their contacts has been discussed on numerous occasions. Both the Blood Products Advisory Committee and the Biological Response Modifiers Advisory Committee, Xenotransplantation Subcommittee, have recommended that additional questions should not be added to the donor history questionnaire. **The AABB agrees with the advisory committee conclusions that additional questions should not be added to the donor history questionnaire.**

Because the blood banking community is concerned 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. This task force has representatives from America's Blood Centers, American Red Cross, American Blood Resources Association, liaisons from the CDC and the FDA, and includes specialists in health survey design. This task force has reviewed the proposed xenotransplant questions to be asked of blood donors and believes that the public will not understand the proposed questions.

The task force also conducted focus group evaluations of these questions to determine donor comprehension and reaction. Focus group participants concluded that it was impractical and foolish to ask these questions of all donors in order to detect a small number of individuals who are theoretically at risk. They also concluded that the

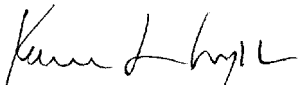
proposed questions were too long and recommended that if questions must be added to the questionnaire, the questions would need to be revised and reworded as multiple questions.

As previously noted, the donor history questionnaire is already very complex, and the AABB is concerned that the addition of several complex questions screening for marginal theoretical risk may distract from the efficacy of the donor questions for documented risk such as known viral transfusion transmitted disease. The xenotransplant recipient and contacts are known to the institutions and programs that initiate and support the transplant. These institutions have close contact with clinical trial participants, and they have the means to notify the individuals at risk that they must not donate blood or tissue. This would be far more efficient than asking specific questions of the millions of individuals who donate blood.

The AABB requests that the guidance be revised to include a statement that expressly relieves blood collecting agencies from questions about contact with xenotransplant recipients and reinforce that the message of deferral is the responsibility of the transplantee.

The AABB thanks the agency for this opportunity to comment. Should you have any questions or wish to discuss any of the comments further, please contact Kay Gregory, Director, Regulatory Affairs at 301-215-6522 or kayg@aabb.org.

Sincerely,



Karen Shoos Lipton, JD
CEO

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