

January 8, 2003

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

Re: Docket No. 02D0428: An Acceptable Circular of Information for the Use of Human Blood and Blood Components

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, hospitalbased 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.

AABB supports the Food and Drug Administration's (FDA) recognition of the *Circular* of *Information for the Use of Human Blood and Blood Components*, dated July 2002, as acceptable for use by manufacturers of blood and blood components intended for transfusion, and appreciates FDA's efforts to make this document available to blood centers for their use in the labeling process.

Thank you for the opportunity to comment.

Sincerely,

Karen Shoos Lipton, JD Chief Executive Officer

020-0428



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