AMERICAN
ASSOCIATION
OF BLOOD BANKS

March 3, 2001

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

Re: Docket #00D-1679: Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives

To Whom It May Concern:

The American Association of Blood Banks (AABB) appreciates the opportunity to submit written comments to the Food and Drug Administration (FDA) on its Draft Compliance Guidance for FDA Employees and Industry on Blood Donor Incentives.

The AABB is the professional association for approximately 2000 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8000 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than eighty percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety and ensure the availability of the nation's blood supply.

The AABB supports the goal of assisting both FDA staff and blood establishments in protecting the safety of the blood supply and establishing policies with the intent of promoting consistency within the blood community. Policies relating to blood donor incentives are extremely important, and we have been anticipating publication of this information.

The AABB questions whether publication of this information in a Compliance Policy Guide is the appropriate mechanism for disseminating this information to blood banks. The Compliance Policy Guide contains information intended for FDA staff, and while some blood banks may be aware that the Office of Regulatory Affairs (ORA) publishes the Compliance Policy Guide, it is unlikely they would consult this source in looking for information about donor incentives. Most blood banks expect to examine either the Code of Federal Regulations or Center for Biologics Evaluation and Research (CBER) guidance documents when they need assistance. It is our understanding that guidance

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

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documents are intended to provide interpretation and explanation of regulations. **We suggest that Blood Donor Incentives should also be issued as a CBER Guidance to Industry rather than appearing solely in the ORA Compliance Policy Guide.**

We have the following comments with regard to content of the draft compliance policy.

In the Policy section, the document states, "It is also not relevant if the incentive goes only to donors who are successful in donation or if all donors who present to donate receive the incentive." We disagree with this statement. We believe that offering an incentive to all people who present at a donation site, rather than offering the incentive only to those who successfully donate, removes the motivation to donate merely to receive the incentive. The donor history interview has been recognized as one of the pillars of safety in the blood supply, and the ability to obtain accurate information in this process should not be compromised by the promise of receiving the incentive only if the donation is successful.

Additional clarification of "readily convertible to cash" should be included. For example, we would like clarification of whether an item is deemed "readily convertible to cash" if the recipient must travel some distance (eg, out of town) to try to sell the item. Does "readily convertible" apply if a person must spend money, for instance, to advertise an item in order to try to sell the item?

Examples of Incentives, G, describes escalating incentive programs. The example given is unclear. Does the policy statement intend to establish that a watch is equivalent to "monetary payment?" In most situations, watches distributed at a donation site are of minimal value, not readily convertible to cash and, therefore, would not constitute monetary payment. Please clarify and expand on this example.

It is our understanding that the FDA is willing to consider whether a particular donor incentive is acceptable if a blood center wishes to consult with the agency before it implements the new incentive. It also would be helpful if the FDA provided contact information for such consultation.

The American Association of Blood Banks appreciates the opportunity to comment on the Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives. Any questions or comments may be directed to Kay Gregory, Director, Regulatory Affairs, AABB, at 301-215-6522 or *kayg@aabb.org.*

Sincerely,

Karen Shoos Lipton, JD
Chief Executive Officer

aa BB AMERICAN ASSOCIATION OF BLOOD BANKS
8101 Glenbrook Road • Bethesda, Maryland 20814-2749

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