



**American
Red Cross**

National Headquarters

5276 '01 MAR 19 P1:41

March 16, 2001

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

**RE: Draft Compliance Policy Guidance for FDA Employees and
Industry on Blood Donor Incentives. Docket # 00D-1679 [65 Fed. Reg.
3605; January 16, 2001]**

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) Draft Compliance Policy Guidance on blood donor incentives (draft guidance or draft). The draft is intended to provide guidance to FDA Investigators and the blood banking community on evaluating blood donor incentives that "may consist of cash or other incentives".

The American Red Cross, through its 36 Blood Services Regions, supplies approximately half of the nation's blood products for transfusion. Recruiting and retaining volunteer donors willing to give these crucial gifts to patients who need them is a key aspect of our effort to provide the safest possible blood and blood products. Thus, we appreciate the opportunity to provide our views to the Agency.

ARC believes strongly that a volunteer blood supply is essential to maintaining the safest blood supply. We recommend that a donor should be "incentivized" to donate blood because of the important role it plays in saving lives and helping one's community. Incentives other than this should be of little value and should be given in the spirit of thanking a donor for their donation. While the draft guidance has touched on important factors to consider when evaluating incentives, a more thorough approach would be far more beneficial to both FDA investigators and to the blood banking community. Specifically, we call upon the FDA to codify in regulation specific criteria that would outline what the Agency considered to be a monetary payment.

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On January 13, 1978, FDA published in the *Federal Register* (43 FR 2142) requirements that blood and blood products intended for transfusion include a statement on the labels that indicated whether the products were collected from paid or volunteer donors. These labeling requirements were codified at 21 CFR 606.121(c)(5). The regulation defines a "paid donor" as a person who receives monetary payment for a blood donation. Examples of what did not constitute monetary payment were outlined at 21 CFR 606.121(c)(5)(iii) and included time off from work, membership in blood assurance programs, and cancellation of non-replacement fees. Additionally, the preamble to the final regulation noted that lotteries or raffles and non-monetary rewards associated with product promotion would not be considered monetary incentives (Final Rule, 43 FR 2142, 2143).

The blood banking community, public health concerns, and the nature of the collection, processing, and distribution of blood products have changed dramatically since these regulations were finalized. Additionally, the expansion of the Internet now allows for almost instant access and transfer of many items that could not be so readily obtained when the regulation was finalized in 1978. There now exists a significant need to reexamine and update the entire regulation so that specific criteria are available to Agency personnel and the blood banking community as to what constitutes a monetary payment. The Draft Guidance document does not elucidate specific criteria and, thus, provides little information to FDA employees or the blood banking community as to the Agency's thinking on what constitutes monetary payment or items that are readily convertible to cash.

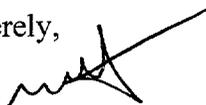
The draft guidance outlines several factors to consider when determining whether an incentive is readily convertible to cash. For purposes of inspection, these factors rely heavily on an investigator's judgment, rather than documents that are obtainable through a typical investigation. Clearly, the value of many incentives and the ability to convert them to cash will vary considerably. For example, the draft states: "it is well known that a market exists for tickets to many professional and collegiate sports events". Further, the guidance notes that free tickets for the theater (e.g., symphony or opera performances) are generally not readily convertible to cash. However, the value of a theater ticket may vary widely among potential blood donors or others who would be willing to purchase such tickets from a donor. The incentive to donate for such individuals might be equal to that for individuals donating to receive sports tickets. In fact, a simple search of certain Internet sites finds that opera tickets are, in fact, readily available for sale and, thus, convertible to cash. Determining whether these items could have been converted to cash, or how much value an individual donor may have placed on them, is unlikely to occur during an inspection. Both blood establishments and FDA investigators would benefit

from more specific guidance and regulation to help ensure consistency among investigations and among blood establishment practices.

The Red Cross understands that FDA has included a review of the Agency's oversight of donor incentives to its "Blood Action Plan" and commends FDA for the inclusion of this issue to the Plan. The Red Cross recommends that FDA move forward with a comprehensive update of regulations pertaining to labeling of blood and blood products as "volunteer" or "paid". Such action will aid FDA employees and blood banking establishments in determining appropriate donor recruitment strategies.

Again, the Red Cross appreciates the opportunity to submit its views and hopes the Agency finds these suggestions constructive. If there are any questions on this letter, or if you wish to meet to discuss these concerns in greater detail, please contact Anita Ducca, Director, Regulatory Relations 703-312-5601 or Craig Mendelsohn, Senior Counsel at 703-312-5788.

Sincerely,



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