

Guidance for FDA Staff and Industry

Compliance Policy Guides Manual

Sec. 230.150

Blood Donor Classification Statement, Paid or Volunteer Donor

Submit written comments regarding this final guidance document to The Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Additional copies of this document may be obtained by sending a request to the above address, or from the Internet at: http://www.fda.gov/ora/compliance_ref/cpg/default.htm

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COMPLIANCE POLICY GUIDE

Compliance Policy Guidance for FDA Staff

CHAPTER - 2

SUB CHAPTER - 230

Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor

This is a new Compliance Policy Guide (CPG) and will be included in the next printing of the manual. It is based on guidance provided to industry representing the Agency's current thinking on blood donor classification statements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. It is intended for FDA personnel and is available electronically to the public.

INTRODUCTION:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 2000). It is a new Compliance Policy Guide (CPG) and will be included in the next printing of the manual. It is based on guidance provided to industry representing the Agency's current thinking on blood donor classification statements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. It is intended for FDA personnel and is available electronically to the public.

BACKGROUND:

In a Federal Register notice dated January 13, 1978 (43 FR 2142), the Agency issued a final rule which required that blood and blood components intended for transfusion include a donor classification statement on the labels to indicate whether the products were collected from paid or volunteer donors. This labeling requirement appears at 21 CFR 606.121(c)(5). The regulation defines a "paid donor" as a person who receives monetary payment for a blood donation [21 CFR 606.121(c)(5)(i)]. A volunteer donor is a person who does not receive monetary payment for a blood donation [21 CFR 606.121(c)(5)(ii)].

The regulation also defines certain benefits that do not constitute monetary payment. Those benefits include time off from work, membership in blood assurance programs, and cancellation of non-replacement fees, as long as the benefits are not readily convertible to cash [21 CFR 606.121(c)(5)(iii)].

The requirement that the label of blood and blood components indicate whether the product came from a volunteer or a paid donor applies only to blood and blood components intended for transfusion, such as Whole Blood, Red Blood Cells, Fresh Frozen Plasma, Platelets, and Cryoprecipitated AHF. The donor classification labeling requirement does not apply to products that will be used for further manufacturing, such as Source Plasma.

As used in this document, the term incentive means anything a donor receives for donating blood other than those items a donor would ordinarily receive during the blood donation process. For example, refreshments provided by the blood collection facility would not be considered to be a donor incentive.

POLICY:

Paid Donors

As stated in the regulation cited above, if a donor receives monetary payment for a blood donation, all products collected from that donor that are intended for transfusion and that are collected during the donation at which the donor received the monetary incentive must be labeled with the "paid donor" classification statement. Monetary payment includes cash, in any amount, or items that are readily convertible to cash. The regulation does not make any distinction regarding where the payment comes from, such as the blood center or the sponsoring organization.

All monetary payments to the donor would require the blood and blood components to be labeled with a "paid donor" classification statement, regardless of the dollar value of the incentive. The nature of the population (the type of people) attracted by the incentive should not be considered in determining whether an incentive is a monetary payment. FDA considers all monetary payments to blood donors to require a "paid donor" label statement on the blood, whether or not the incentive is offered only to donors who are successful in donating or if all donors who present to donate receive the incentive.

If a monetary payment in any amount is made to a group to which the donor belongs, this would generally be considered a monetary payment to the donor. An exception to this is reimbursement to the sponsoring organization for costs directly associated with the blood drive, such as advertisement or refreshments for the donors. FDA would not consider reimbursement for costs directly associated with the blood drive to be a payment to the donor, even if the donor belongs to the sponsoring organization.

Volunteer Donors

The regulation specifies benefits that would not require the "paid donor" classification statement, as long as the benefits are not readily convertible to cash. These benefits are 1) time off from work, 2) membership in blood assurance programs, and 3) cancellation of non-replacement fees. Products collected from blood donors who have received such benefits may be labeled with the "volunteer donor" classification statement.

Other incentives that would not require the "paid donor" classification are described in the

preamble to the final regulation mentioned above. These include 1) lotteries or raffles, regardless of the value of the prize to be given away [Final Rule, 43 FR 2142, 2143 (1978)] and 2) non-monetary rewards associated with product promotion (id.).

If an incentive is not cash and is not a benefit specifically described in the regulation, the blood can be labeled with the “volunteer donor” classification statement unless the incentive is readily convertible to cash. If the incentive is cash or is readily convertible to cash, the blood must have the “paid donor” classification statement on the label.

Factors to Consider

If the donor receives an incentive other than cash, the incentive should be evaluated to determine if it is readily convertible to cash. Some factors to consider when determining whether an incentive is readily convertible to cash are as follows:

A Is the incentive transferable?

An incentive is considered transferable if someone other than the donor can use it. If the incentive is not transferable, it can only benefit the donor. Because the incentive is not transferable, it presumably cannot be sold and therefore cannot be converted to cash. If the incentive is not transferable, the blood from the donation can be labeled with the “volunteer donor” classification statement.

B Is the incentive refundable or redeemable for cash?

An incentive is considered refundable or redeemable if the donor can take the incentive to the organization or business that provided or sponsored the incentive and receive cash back. If the incentive is refundable or redeemable for cash, the incentive would generally be considered to be readily convertible to cash. Blood from a donor who received an incentive that is readily convertible to cash must be labeled with the “paid donor” classification. For example, a donor may receive a gift certificate for the purchase of a CD at a local record store. If the donor can obtain cash from the record store in exchange for the certificate, the gift certificate would be an incentive that is readily convertible to cash and the all products collected from the donor must show the “paid donor” classification statement.

C Does a market exist for the incentive?

1. If no market exists for the incentive, it would generally not be considered to be readily convertible to cash, and the blood could be labeled with the “volunteer donor” label statement.
2. If a market exists in which a donor could sell the incentive, how readily can it be converted to cash? The blood must include a “paid donor” label statement if the incentive is “readily convertible to cash” (emphasis added). If an incentive is convertible to cash, but this would require a significant effort on the part of the donor, the incentive may be one which would not require the blood to have a “paid donor” statement.

Examples of Incentives

The Center for Biologics Evaluation and Research (CBER) has reviewed a number of actual donor incentives and describes below its findings on whether the incentive would require the blood to have the “paid donor” classification statement. It is important to remember that these conclusions were based on the facts of a particular case and that the facts of a different scenario may result in a different determination of whether the blood should be labeled as collected from a paid or volunteer donor.

A. Event tickets

If the tickets or vouchers are transferable, whether a market for the tickets exists is an important factor. It is well known that a market exists for tickets to many professional and collegiate sports events. The market is usually an easily accessible one, as it is common to see potential sellers and buyers of tickets at the entrance to the sports facility prior to an event. Generally, tickets or vouchers to sporting events would require blood to have a “paid donor” label statement.

Tickets or vouchers for other events may or may not require a paid donor label, depending on whether the tickets or vouchers are transferable, convertible to cash, and whether a market exists for the ticket. Free tickets for movie theaters are generally not readily convertible to cash, so generally may be considered benefits that would not require a “paid donor” label. Ticket vouchers for symphony or opera performances may require a “paid donor” label to be placed on the products if an accessible market exists for the tickets and they are transferable.

B. Compact discs compliments of a music store.

Compact discs (CDs) and similar incentives may be considered “nonmonetary rewards associated with product promotion” and would not require a “paid donor” label statement [Final Rule, 43 FR 2142, 2143 (1978)] if they are provided compliments of a particular business. If the CDs are not associated with product promotions and a market exists for the CDs, the blood may require a “paid donor” label statement.

C. Reduced room rates compliments of a hotel

If the benefit is not refundable or redeemable for cash at the hotel, but is a discount in the normal price of the hotel room, the incentive would generally be considered a non-monetary benefit and would not require the blood to have the “paid donor” label statement. If the discount is transferable and a readily accessible market exists for discounted room rates for the particular hotel, the incentive would likely be considered readily convertible to cash. Blood from a donor who received an incentive that is readily convertible to cash must show the “paid donor” label statement.

D. Frequent flyer miles

Frequent flyer miles are generally not transferable. While a market may exist for the miles, it is not one that is readily available for the limited number of miles provided as blood donor

incentives. This incentive would generally not require a “paid donor” label statement on the blood.

E. Medical tests

Blood collection facilities have offered medical tests, such as cholesterol screenings, as incentives for blood donors. A test performed or one for which blood is drawn at the time of donation is an incentive that is not transferable. Therefore, the benefit is not readily convertible to cash and would not require a “paid donor” label statement. Other variations of this benefit may not result in a similar conclusion, such as a voucher for a free screening test. This section does not refer to tests that are performed as part of the donation process, such as viral marker screening tests.

F. Escalating incentive programs

In some programs, the incentive escalates in value as the number of donations increases. For example: the incentive for the first donation may be a t-shirt, the incentive for the second donation may be a coffee cup, and the incentive for the tenth donation may be a television set. Donations at which the donor received an incentive that would not be considered monetary payment could be labeled with the “volunteer donor” label. Donations at which the donor received an incentive that would be considered monetary payment because it is cash or readily convertible to cash must be labeled with the “paid donor” label statement. In the example given, the blood collected at the first and second donations could generally be labeled with a “volunteer donor” label statement, because t-shirts and coffee mugs are usually not readily convertible to cash. The blood collected at the donation at which the donor received a television set would generally require a “paid donor” label statement, because a television set is usually readily convertible to cash.

G. Scholarship programs

Blood organizations have offered scholarship incentives to high schools that sponsor blood drives. If the scholarship is established such that the student recipient does not receive cash, but rather the scholarship money is transferred directly to the college, university, or other learning establishment that the student attends after high school, the incentive would not be considered to be readily convertible to cash and the blood collected could be labeled with the “volunteer donor” label statement.

REGULATORY ACTION GUIDANCE:

As stated in the Investigations Operations Manual (IOM) investigators may include observations regarding blood and blood components labeling on FDA 483s (Section 512.1, item 10). If an investigator finds that a blood establishment clearly has provided monetary payment, including an incentive that is readily convertible to cash, to a donor of blood intended for transfusion, but the label does not show the “paid donor” classification statement, the investigator may cite the firm for failing to label the blood or blood component appropriately.

As stated in the Regulatory Procedure Manual (RPM), districts should seek concurrence from CBER prior to issuing warning letters citing labeling violations.

Issued: [Insert Date Signed by ACRA in format mm/dd/yyyy]