

Compliance Policy Guides Manual
Compliance Policy Guide
Draft Compliance Policy Guidance
For
FDA Staff and Industry
(Not for Implementation)

Blood Donor Incentives
Sec. 230.150

Comments and suggestions regarding this draft document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

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CHAPTER - 2
SUB CHAPTER - 230

Sec. 230.150 Blood Donor Incentives

This draft guidance to FDA employees and industry represents FDA's current thinking on blood donor incentives. 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 an approach satisfies the requirements of the applicable statute, regulations, or both. The guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (65 FR 56468, September 19, 2000) (21 CFR 10.115(g)(2)); the draft guidance has been designated as Level 1 guidance.

INTRODUCTION:

This draft compliance guidance document is an update to the Compliance Policy Guides Manual (August 2000). It is a new CPG and when finalized will be included in the next printing of the manual. It is based on guidance provided to FDA employees and industry representing the Agency's current thinking on blood donor incentives. 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 statute 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 instituted 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. 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, described in 21 CFR 606.121(c)(5)(iii), 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.

The requirement that the label of a blood product indicate whether the product came from a volunteer or a paid donor applies only to blood and blood components intended for transfusion. It does not apply to products that will be used for further manufacturing, such as Source Plasma.

POLICY:

As discussed in the regulation cited above, if a blood establishment provides monetary payment to a donor, 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 should be labeled with the "paid donor" classification statement. These products include Whole Blood, Red Blood Cells, Fresh Frozen Plasma, and Platelets.

Monetary payment includes cash, in any amount, or items that are readily convertible to cash.

If a cash payment in any amount is made to a group to which the donor belongs, this would be considered a monetary payment to the donor and the products collected from the donor should be labeled with the "paid donor" classification statement.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash.

The regulation also specifically describes benefits that would not require the "paid donor" classification statement, as long as the benefits are not readily convertible to cash. These incentives 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 incentives 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.). These incentives are not considered to be readily convertible to cash.

For other incentives that are not cash and which are not specifically described in the regulation or preamble to the regulation, the product can be labeled with the "volunteer donor" statement unless the incentive can be readily convertible to cash. If the incentive can be readily convertible to cash, the product must have the "paid donor" classification on the label.

Some factors to consider when determining whether an incentive is readily convertible to cash are as follows:

1) Is the incentive transferable? If the incentive is not transferable, it can only benefit the donor. Because it cannot be sold, and thereby be converted to cash, the products can be labeled with the "volunteer donor" statement.

2) Is the incentive refundable or redeemable for cash? If the incentive is refundable or redeemable for cash, it would generally be considered to be readily convertible to cash and the products must be labeled with the "paid donor" classification.

3) Does a market exist for the item? If a market exists in which a donor could sell the incentive, relatively quickly and easily, for cash, the resultant blood would require the "paid donor" labeling.

4) How readily can the item be converted to cash? An incentive would require the products to include a "paid donor" label statement if it is "readily convertible to cash" (emphasis added). If an incentive may be converted to cash, but this would require a significant effort on the part of the donor, the incentive may not be one which would require the products to have a "paid donor" statement.

The dollar value of the incentive and the nature of the population attracted by it are not relevant. It is also not relevant if the incentive goes only to donors who are successful in donating or if all donors who present to donate receive the incentive.

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 products 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 products should be labeled as collected from a paid or volunteer donor.

Examples of Incentives

- A. Symphony or opera performance ticket vouchers.
Free tickets for the theater are generally not readily convertible to cash, and so may be considered benefits that would not require a "paid donor" label [Proposed Rule, 42 FR 11018, 11019 (1977)], unless an accessible market exists for the tickets and they are transferable. Ticket vouchers for symphony or opera performances are generally analogous to theater tickets.
- B. Compact discs compliments of a music store.
Compact discs (CDs) and similar incentives may be considered "nonmonetary rewards associated with product promotion" [Final Rule, 43 FR 2142, 2143 (1978)] if they are provided compliments of a particular business, and so would not require a "paid donor" label statement. If the CDs are not associated with product promotions, the products may require a "paid donor" label statement if a market exists for the CDs.
- 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, it would generally be considered a non-monetary benefit and would not require the products to have the "paid donor" label statement. If the discount is transferable and a market exists for discounted room rates for a particular hotel, it may require the products to 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 products.
- 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, such as vouchers for a free screening test, may not result in a similar conclusion.
- This section does not refer to tests that are performed as part of the donation process, such as viral marker screening tests.
- F. Sports game tickets or vouchers.
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 a blood product to have a "paid donor" label statement.

G. 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, and the incentive for the tenth donation may be a watch. 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 should be labeled with the "paid donor" label statement.

REGULATORY ACTION GUIDANCE:

Citations for deviations from blood and blood products labeling requirements may be included on FDA 483s (IOM 512.1, item 10). If investigators find that a blood establishment clearly has provided monetary payment or an incentive that is readily convertible to cash to a donor of blood intended for transfusion, but the label does not show the classification statement "paid donor", the firm should be cited for failing to label the product appropriately.

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

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