

Compliance Policy Guide CPG Sec. 230.150: Blood Donor Classification Statement, Paid or Volunteer Donor

Guidance for FDA Staff

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2019-D-4090.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION:

The purpose of this Compliance Policy Guide is to provide guidance to FDA staff on the labeling of blood and blood components intended for transfusion with the appropriate donor classification statement (i.e., “paid donor” or “volunteer donor”).

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA’s current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. The use of the word “should” in FDA’s guidances means that something is suggested or recommended but not required.

II. 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 container label to indicate collection from a “paid donor” or “volunteer donor.” This labeling requirement appears at Title 21 of the Code of Federal Regulations (CFR) 21 CFR 606.121(c)(8)(v). The regulation defines a “paid donor” as a person who receives monetary payment for a blood donation (21 CFR 606.121(c)(8)(v)(A)). A “volunteer donor” is a person who does not receive monetary payment for a blood donation (21 CFR 606.121(c)(8)(v)(B)).

The regulation also states that benefits such as time off from work, membership in blood assurance programs, and cancellation of non-replacement fees that are not readily convertible to cash, do not constitute monetary payment. (21 CFR 606.121(c)(8)(v)(C)).

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The requirement that the container label of blood and blood components indicate whether the donation was collected from a “volunteer donor” 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 blood and blood components intended for further manufacturing use, such as Source Plasma and recovered plasma.

For the purposes of this guidance, the term incentive means anything a donor receives for donating blood and blood components except for those items a donor would ordinarily receive during the blood donation process. For example, refreshments provided by the blood establishment would not be considered a donor incentive.

III. POLICY:

A. Paid Donors

Under 21 CFR 606.121(c)(8)(v), if a donor receives monetary payment for a blood donation, all blood and blood components that are intended for transfusion and collected during the donation at which the donor received the monetary payment must be labeled with the “paid donor” classification statement. Monetary payment includes cash, in any amount, and incentives that are readily convertible to cash. The regulation does not distinguish the source of the payment, for example, the blood establishment or the organization sponsoring a blood drive.

Regardless of the amount, all monetary payments to a donor require the blood and blood components intended for transfusion to be labeled with a “paid donor” classification statement. All monetary payments to a blood donor require a "paid donor" statement, whether or not the monetary payment is offered only to donors who complete the donation process or to all donors who present to donate.

If a monetary payment in any amount is made on behalf of the donors to a group to which the donors belong, this would generally be considered a monetary payment to the individual donors. For example, a cash payment to the “holiday party” fund of a business that is hosting a blood drive and whose employees are donors would be considered monetary payment to the donors. An exception to this is reimbursement to an organization sponsoring a blood drive for costs directly associated with the blood drive, such as for advertising or purchasing refreshments for the donors. FDA would not consider reimbursement to the sponsoring organization for costs directly associated with a blood drive to be a payment to the donor, even if the donor belongs to the sponsoring organization.

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B. Volunteer Donors

Under 21 CFR 606.121(c)(8)(v)(C)), certain benefits are identified that are not readily convertible to cash and do not constitute monetary payment. These benefits are 1) time off from work, 2) membership in blood assurance programs, and 3) cancellation of non-replacement fees (i.e., the cancellation of hospital charges related to any future blood transfusions needed by the donor). Blood and blood components collected from blood donors who have received such benefits should be labeled with the “volunteer donor” classification statement.

Other examples of incentives that would not require the “paid donor” classification are described in the preamble to the final regulation (43 FR at 2142-43). These include 1) lotteries or raffles, regardless of the value of the prize to be given away; and 2) non-monetary rewards associated with product promotion, such as promotional items bearing the company logo of the blood establishment or the sponsoring organization. Blood and blood components from donors who have received such benefits or other benefits not readily convertible to cash should be labeled with the “volunteer donor” classification statement if the incentive is not cash or readily convertible to cash. If the incentive is cash or is readily convertible to cash, the blood and blood components intended for transfusion must have the “paid donor” classification statement on the label.

C. 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:

1. 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. If an incentive is not transferable, it presumably cannot be sold and therefore is not readily convertible to cash. If the incentive is not transferable, the blood and blood components collected from the donor and intended for transfusion should be labeled with the “volunteer donor” classification statement.

2. Is the incentive refundable or redeemable for cash?

An incentive is considered refundable or redeemable for cash if the donor can return the incentive to the organization or business that provided the incentive and receive cash. If the incentive is refundable or redeemable for cash, the incentive is considered readily convertible to cash. Blood and blood components intended for transfusion 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 from a store towards a future purchase. If the donor can obtain cash from the store in exchange for the certificate, the gift

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certificate is an incentive that is readily convertible to cash and the blood and blood components collected from the donor and intended for transfusion must be labeled with the “paid donor” classification statement.

3. Does a market exist for the incentive?

If a market exists in which a donor could sell the incentive, you should consider whether the incentive is readily convertible to cash. The blood and blood components intended for transfusion must include a “paid donor” label statement if the incentive is readily convertible to cash. If an incentive is convertible to cash, but this would require a significant effort on the part of the donor, the incentive may not require the blood and blood components to have a “paid donor” statement.

D. Examples of Incentives

The following examples are provided based on the Center for Biologics Evaluation and Research’s (CBER’s) experience reviewing donor incentives. It is important to remember that our recommendations are based on the specifics of the example provided, and a different scenario may result in a different determination of whether the blood and blood components should be labeled with the “paid donor” or “volunteer donor” classification statement.

1. Event tickets

If the tickets are transferable, you should consider whether a market exists for the tickets. It is well known that a market exists for tickets to many professional and collegiate sporting events, music concerts and festivals, and major amusement parks. In these situations, the market is usually an easily accessible one. For example, it is common to see potential sellers and buyers of tickets at the entrance to these events. In addition, there are several internet-based venues for selling and buying such tickets. Therefore, providing tickets to such events would generally require a “paid donor” label statement.

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

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2. Reduced room rates for a hotel

If the reduced room rate is not refundable or redeemable for cash at the hotel, the incentive would generally be considered a non-monetary benefit and would not require the “paid donor” label statement. However, if the reduced room rate 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 and blood components collected from a donor who received an incentive that is readily convertible to cash must have the “paid donor” label statement.

3. 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 accessible for the limited number of miles provided as blood donor incentives. Use of frequent flyer miles as an incentive would generally not require a “paid donor” label statement.

4. Medical and health-based incentives

Blood establishments have offered a variety of medical and health-based incentives for blood donors. One common example is the offer of a laboratory screening test (e.g., a cholesterol screen). A laboratory screening test performed, or one for which blood is drawn, at the time of donation is an incentive that is not transferable. Therefore, the incentive is not readily convertible to cash and would not require a “paid donor” label statement. However, a voucher for a free screening test that would be performed at a later date, may be considered readily convertible to cash if it is transferrable and an accessible market exists. Note that this section does not address tests that are performed as part of the donation process, such as transfusion-transmitted infection screening tests. Incentives granting donors access to systems that aggregate and track their electronic health information (e.g., test results and vital signs from physicians, heart rate data from smartwatches) are not considered readily convertible to cash to the extent that a market does not exist to convert such incentives to cash.

5. Escalating incentive programs

In some programs, incentives escalate 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. Donations at which the donor received an incentive that is not considered monetary payment should be labeled with the “volunteer donor” label. Donations at which the donor received an incentive that is 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

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blood and blood components collected at the first and second donations should generally be labeled with a “volunteer donor” label statement, because t-shirts and coffee mugs are usually not readily convertible to cash. The blood and blood components collected during 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.

6. Scholarship programs

Blood establishments or other organizations may offer scholarship incentives to schools that sponsor blood drives. If the incentive is established such that the scholarship is distributed directly to the school, or the incentive is distributed to a dedicated scholarship fund created by the school, the incentive would not be considered readily convertible to cash and the blood and blood components collected should be labeled with the “volunteer donor” label statement.

7. Gift cards and gift certificates

Gift cards and gift certificates are considered the same for the purposes of this guidance. A gift card incentive is considered a monetary payment if readily convertible to cash. If a gift card is non-transferable, bears the donor's name, and is not redeemable for cash, it would not be considered readily convertible to cash and blood and blood components collected should be labeled with the “volunteer donor” label statement.

Blood establishments collecting blood and blood components in areas where state or local laws require merchants to redeem gift cards/certificates for cash should consider all gift card incentives as readily convertible into cash; therefore, collected blood and blood components require the “paid donor” label statement.

IV. REGULATORY ACTION GUIDANCE:

As stated in the Investigations Operations Manual (IOM), investigators may include observations regarding blood and blood component labeling on FDA 483s (Chapter 5, Subchapter 5.2.3.2.2). 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 and blood components 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 Procedures Manual (RPM), Chapter 4 Advisory Actions (Sec. 4-1-4) divisions within the Office of Biological Products Operations should seek concurrence from CBER prior to issuing warning letters citing labeling violations.

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