

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1679]

DWB

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Certifier	J. Andrews

Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft compliance policy guidance entitled "Sec. 230.150 Blood Donor Incentives." The draft guidance is intended to provide guidance to FDA employees and industry for evaluating blood donor incentives that may consist of cash or other incentives.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. You may fax your request to 301-827-0852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1242.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of January 13, 1978 (43 FR 2142), FDA published a final rule requiring 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 § 606.121(c)(5) (21 CFR 606.121(c)(5)). The regulation defines a “paid donor” as a person who receives monetary payment for a blood donation (§ 606.121(c)(5)(i)). A volunteer donor is a person who does not receive monetary payment for a blood donation (§ 606.121(c)(5)(ii)). The regulation also defines certain benefits that do not constitute monetary payment. Those benefits, described in § 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. Products collected from blood donors who have received such incentives may be labeled with the “volunteer donor” classification statement.

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.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash. The draft guidance document provides FDA employees and industry with some examples of incentives and identifies some factors to consider when determining whether an incentive is readily convertible to cash. The draft guidance advises FDA employees that they may cite deviations from blood and blood product labeling requirements on Form FDA 483 (inspectional observations).

II. Significance of Guidance

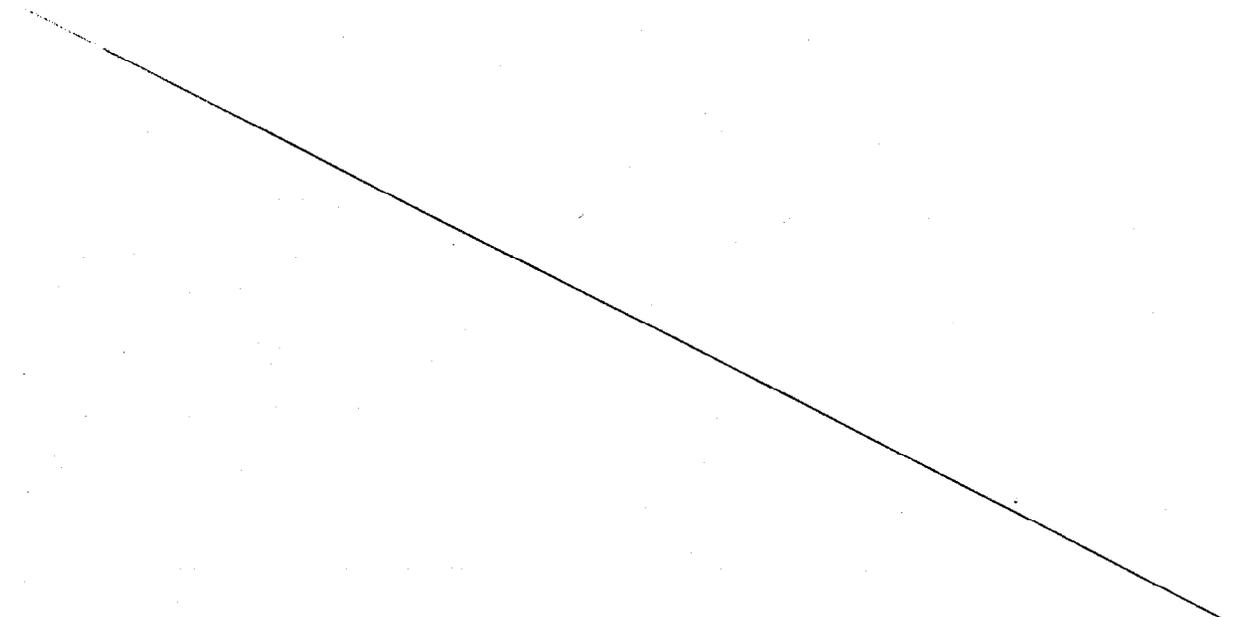
This draft guidance document represents the agency’s current thinking on blood donor incentives. The draft guidance is not intended for implementation at this time. It does not create

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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is being issued as Level 1 guidance consistent with GGP's.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. Submit to the contact person (address above) written comments regarding this draft guidance after *[insert date 60 days after date of publication in the Federal Register]*. Such comments will be considered when the draft guidance is finalized. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance on the Internet may access the draft at http://www.fda.gov/ora/compliance_ref/cpg/default.htm.

Dated: 01/05/01

January 5, 2001



Dennis E. Baker
Associate Commissioner for Regulatory Affairs

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