

March 6, 2001

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Frances Pratt
510 Coventry Road, Apt 15-D
Decatur, Ga 30030

To whom it may concern,

Re: Draft Compliance Policy for Blood Donor Incentives Sec.230.150

I recognize that the draft compliance policy is not intended to bind any person or organization including the FDA. It is a necessary policy, however, because 21 CFR 606.121(c) is so vague. Therefore, the industry and the employees of the FDA need additional guidance. Clarity is also important, as blood establishments can be cited for failure to abide by the regulation. Therefore, I would like to suggest some clarification to the draft guidance.

I agree with the general factors listed in the guidance that help determine whether or not an item is readily convertible to cash. Although these factors are helpful, they are not as clear and informative as the actual examples given in the guidance. However, I find some of the examples to be unclear.

Example A includes symphony, opera, and theatre tickets. These are not considered to be readily convertible to cash because there is not an obvious market. Example F, on the other hand, states that sports game tickets would be readily convertible to cash because a more obvious market exists. I do not understand the difference between the two types of tickets, as any ticket can be sold to someone who wants it. In fact, opera and symphony tickets are often more expensive than a sports game ticket. The guidance states that the dollar value of the incentive or the nature of the population attracted is not relevant to determining whether an item is considered to be readily convertible. However, it seems that that is precisely the difference between tickets to the opera or symphony and tickets to sports events. The sports tickets are a more popular incentive.

In addition, the purpose of the guidance is to help direct the FDA employees and blood establishments. The difference between the types of tickets is too narrow to assist the establishments and employees make decisions. For example, many different types of tickets could be offered as incentives, and many would fall between these two extremes, such as popular concert tickets.

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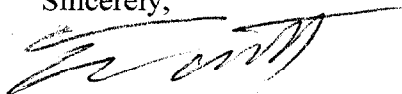
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I believe that almost all tickets should require the donors to receive a "paid donor" designation, as all tickets can be sold for cash, and the distinction between the types of tickets is simply the population attracted.

My second concern is contained in example B. That example indicates that compact discs would be considered "product promotion" if they were donated by a particular business, and a monetary incentive if they were not donated by a particular business. I recognize that the preamble to the Final Rule, 43 FR 2142 states that non-monetary rewards associated with product promotion are not considered to be easily convertible to cash. However, all CD's are easily convertible to cash because they can be sold as used to many different music stores. Many music stores have special CD's that are used in product promotions. They are typically marked as product promotions and state that they cannot be resold. In addition, they will typically have different songs on them than regular CD's. Therefore, I believe that a CD should be considered a product promotion if it is specifically marked as a product promotion, but if it is a regular CD that could be purchased, then it would be considered freely transferable, regardless of whether or not it came from a particular business.

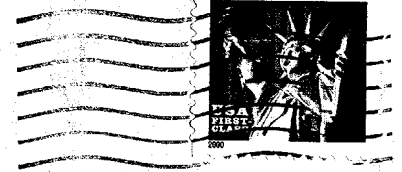
I hope these suggestions are helpful. Thank You.

Sincerely,

A handwritten signature in black ink, appearing to read "Frances Pratt", written in a cursive style.

Frances Pratt.

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