New York *Blood Center*

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March 19, 2001

Via Fax to 301-827-0482 and Express Carrier

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Draft Compliance Policy Guidance – Sec. 230.150 Blood Donor Incentives

Dear Sir/Madam:

On behalf of the New York Blood Center, Inc. (**"NYBC"**), the independent blood center supplying volunteer donor blood to the nation's largest metropolitan area, we wish to share the following comments and suggestions concerning the above mentioned draft.

First, we welcome and support FDA's efforts to reexamine periodically the requirements announced in the 1978 Federal Register notice and to offer guidance to blood collection centers that take into account issues salient to the twenty-first century, such as medical screening as a form of incentive.

Second, blood collection centers welcome guidance that will help us communicate effectively with organizations that sponsor blood drives. Most importantly, we seek guidance that will further our shared mission of providing safe and effective blood products. Relatedly, for us to communicate effectively with blood drive sponsors, we seek guidance that is clear, comprehensive, responsive and realistic.

By way of background, although blood collection centers remain fully responsible for the administration and consequences of compliance with the regulations and guidelines of FDA and other regulatory authorities, the actual suppliers of donor incentives are typically the corporate and community groups (i.e., schools, religious organizations, unions, etc.) that sponsor blood drives. This means blood collection centers must in effect "police" the sponsoring organizations. The blood drive sponsors assume the role of marketers who develop and provide the incentives that recruit the "raw materials" for our FDA/other-regulated products. FDA's guidance should make specific mention that the scope of the guidance covers all incentives, irrespective of the source.

Third, we welcome FDA's focus on labeling (i.e.,"volunteer donor" vs. "paid donor") and FDA's emphasis on an objective standard based on the unacceptability of labeling as volunteer donor blood, blood collected from a donor who was offered cash, a cash equivalent or an item readily

convertible to cash. The examples below suggest that the assumptions in certain parts of the guidance may not be warranted and should therefore be further qualified. This observation is particularly applicable to the incentive of time off from work (see below).

Fourth, we recommend that FDA consider extending its focus to donor suitability. Over the years, FDA has implemented effective regulations and guidance on donor suitability. The issue of donor incentives raises a different, more subjective concern. That is, are the incentives likely to serve as an inducement for a potential donor to misrepresent the truth about his/her suitability to donate in order to obtain the incentive. To that end, NYBC recommends that FDA extend the guidance as follows: (a) offering incentive to all who present to donate (i.e., deferrals as well as successful donors), (b) taking into account the dollar value of the incentive, and (c) where applicable, considering the probability of winning a high-value item (e.g., through a raffle or lottery). We, therefore, recommend deletion of the two sentences:

> 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.

We also note several more specific observations:

Time Off Work. Time off from work may be convertible to cash. Although time off directly connected to the donation event is benign, it is common practice that a repeat donor can accumulate a number of "days off". In a company with a policy that reimburses unused time off (at the end of the year/at termination/at retirement), these "blood days" may therefore be directly convertible to cash. Not only would such a donor be considered a paid donor, but we believe the motivational issues should not be overlooked.

Raffles/Lotteries. A raffle, especially if offered only to donors, with low odds (1:50, etc.) and a prize of "unlimited" value (e.g., projection TV, week's vacation to Bermuda, etc.) create a significant risk of less than truthful medical history responses. This risk increases if the raffle prize is available only to actual donors. This concern does not apply to the provision of tickets to government-sponsored lotteries, where the prize may be of great value but the chance of winning is insignificant. (Of course, following FDA's logic, should a blood donor receive what turns out to be the winning ticket, would a recall of his/her blood be required?)

Sports and Entertainment. We assume the references to sports events and opera are merely meant as illustrations of marketability. Of course, local situations may reveal a hot market for opera tickets and no interest in a sports event. In any case, to reduce or eliminate the possibility of transferability, we suggest that FDA consider requiring that such tickets, as well as other items like discount coupons, be labeled as "non-transferable, non-redeemable, non-marketable, non-convertible to cash."

Grades or class credit. Although we strongly support encouraging young people to foster community service by becoming blood donors, we believe that increasing class grades or offering class credit might serve as an inducement to misrepresent the truth. We seek FDA guidance on this issue.

Guidance to Industry. NYBC would appreciate FDA's issuing formal regulations or Guidance to Industry on donor incentives, rather than the less direct mechanism of a field guidance.

NYBC very much appreciates the opportunity to comment provided by FDA's December 29, 2000, publication of the draft Guidance.

Sincerely yours,

Miriam Sparrow, Esq.
General Counsel

and

Edwin W. Streun, Director
Regulatory Affairs

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