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Phone: 412 -209-7300

The Institute For Transfusion Medicine

March 15, 2001

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

RE: Blood Donor Incentives, Section 230.150

Thank you for the opportunity to comment on the FDA's current thinking on blood donor incentives as outlined in the Office of Regulatory Affairs' draft Compliance Policy Guidance for FDA Staff and Industry. The following are comments from both LifeSource Blood Services (Chicago, IL) and Central Blood Bank (Pittsburgh, PA).

We appreciate the fact that ORA has tried to tackle a very difficult issue and establish some parameters for the evaluating donor incentives. We believe it is critical to maintain a *volunteer* donor base and protect the *integrity* of the donor's medical history. We agree that cash in any amount requires "paid donor" labeling. However, the evaluation of "readily convertible to cash" is much more difficult. ORA has provided several litmus tests for this convertibility, but some of them too have inherent problems:

Transferability — This is difficult to control in practice as low incentive items like T-shirts and movie passes can easily be given to someone else.

Marketability — The examples given, opera tickets vs. sports tickets, vary widely in how attractive they are to a buyer and depend on geography. We see marked differences just between Chicago and Pittsburgh.

Although ORA dismisses as irrelevant whether or not an incentive is given to all who attempt to donate or only those who successfully donate, we must respectfully but strongly disagree. We have carefully guarded the integrity of the medical history and allowing a donor's perception of the value of an incentive to affect their choice of answers to medical history questions is unacceptable.

We are also concerned about allowing all "time off work" incentives. We would suggest that you consider limiting the time off work to that needed for the donation process and reasonable travel time to and from the donation site.

We believe the draft Compliance Policy is a good starting point, but we ask that the comments noted above be considered in revising this policy. Thank you very much.

Sincerely,

Patricia Galsky

Patricia Galsky
Quality Department

00D-1679

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SPH42

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