From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, August 30, 2004 12:51 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted],

I suppose the “fraction of a blood donation” amount could have been suggested for clarity, but if it’s confusing feel free to take it out. It is not required, and we do not know the source that requested it.

I hope this information is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: CDER DRUGINFO
Sent: Friday, August 13, 2004 5:03 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Wednesday, August 04, 2004 4:05 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: We ([Redacted]) are currently revising and examining our IRB guidelines. In our guidelines we discuss the amount of blood that may be withdrawn in terms of cc's, teaspoonsful, and as a fraction of a blood donation. The latter amount (fraction of a blood donation) was in our guidelines as the result of an unnamed FDA "person's" request. I cannot find any justification for expressing blood in this way and find it confusing and uninformative. However, before removing the amount in term of blood transfusion, I wanted to make sure that I was not missing something.
Please let me know if this is a requirement or recommendation and what is the source, if any.
Thanks. [Redacted]