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Maimonides

February 16, 2001

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

Re: Draft Compliance Policy Guidance - Blood Donor Incentives (Sec. 230.150)

To Whom It May Concern:

This letter is being submitted in response to the recently published Draft Compliance Policy Guidance on Blood Donor Incentives.

My comment relates to the third paragraph of the section entitled "Policy" which currently provides as follows: "If a cash payment in any amount is made to a group to which the donor belongs, this would be considered a monetary payment to the donor and the products collected from the donor should be labeled with the 'paid donor' classification statement (emphasis added)." I believe that underlined language in this paragraph is overly broad and is subject to misinterpretation.

As drafted, the language seems broad enough to suggest that even payments made to a group for reimbursement of expenses incurred in conducting a group blood drive would cause all donations made during that blood drive to be considered "paid" donations. For example, since a payment made to a community group to reimburse for expenses in conducting a blood drive (e.g. juice, publications notifying the community of the blood drive, personnel to work the drive) – which would, by definition, never be passed on to the donor/members of such community group – are a "cash payment ... made to a group to which the donor belongs," the language of the new Guidance suggests that the donations by members of that group would be transformed into a "paid" status.

I have spoken about this issue with Ms. Catherine Miller on the telephone, who was very informative and indicated the policy was not supposed to convert such situations to paid donor classification, but she also suggested I follow-up in writing. If the interpretation I mention above is, indeed, not intended by the

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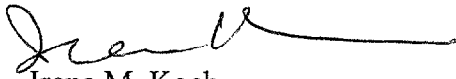
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Guidance, the language of the Guidance should be clarified and narrowed accordingly.

Thank you for your attention to this matter. If you have any further questions, you may reach me at (718) 283-7578.

Sincerely,



Irene M. Koch
Associate General Counsel

cc: Joyce A. Leahy, Esq.
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