

San Diego  
Blood Bank  
A Regional Blood Center



December 16, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. 98N-0607: General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors**

To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's (FDA) notice regarding the draft guidance entitled "General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors" announced in the Federal Register of August 19, 1999.

SDBB disagrees that making guidelines for the notification of donors due to positive test results is within the oversight of the FDA. We agree that donors deferred on the basis of test results must be notified of their deferral status. Most blood establishments already perform this service. However, if this rule is passed it should allow blood establishments the flexibility to perform this notification in the manner they determine best. In some cases, state laws dictate infectious disease notification requirements; and for FDA to impose a different set of criteria may be confusing.

FDA is proposing that donor notification occurs up to three times within 8 weeks. We do not believe this is necessary. There is no danger of the donor donating again even if notification does not occur, as the donor is deferred as soon as the test result is known. A blood establishment also needs flexibility in determining the best way to notify a donor. It is our experience that using certified mail has on some occasions caused to donor to ignore our letters and refuse to contact the San Diego Blood Bank for counseling. Additionally, to require that three attempts be made within 8 weeks is an unnecessarily short time frame especially when additional attempts may not increase the chance of contacting the donor.

FDA is requesting comments regarding the notification of autologous donors with positive test results. We agree that such donors should be notified, but do not agree that direct notification

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may be the best approach. A physician orders such donations, and we have found that it is best to approach the physician and the donor regarding the test results. We urge flexibility in managing the group of donors.

The FDA is proposing that donors be notified based on results of screening questions. This practice is already taking place at the time of screening and does not need to be regulated. It is unnecessary to require additional attempts to notify the donor after the screening process. We would like clarification regarding this proposed rule. Is additional written notification to the donor being proposed?

FDA is proposing the blood establishments obtain a permanent address for each prospective donor. We would like clarification of this rule. Currently, the address obtained at the time of donation is a donor's current address, such as when a college student is away at school, but not necessarily their permanent address. We believe the address we obtain at the time of screening is sufficient for the purposes of notification when required. Additionally, what proof is required? Is a verbal acceptable, or must it be something like a driver's license?

Thank-you for this opportunity to comment on FDA's draft "General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors". If you have any questions, please feel free to contact me or the Director of Quality Assurance/Compliance, Ms Patricia E. Bakke, by phone at 296-6393, or by e-mail at [tmelaragno@bloodbank.org](mailto:tmelaragno@bloodbank.org) or [pbakke@bloodbank.org](mailto:pbakke@bloodbank.org).

Sincerely,



Anthony J. Melaragno, M.D.  
Medical Director/CEO  
San Diego Blood Bank

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Blood Bank**  
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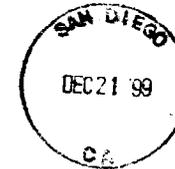
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*Return  
Receipt  
Requested*

**MAIL**



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