

San Diego
Blood Bank
Saving Lives Since 1950



3679 01 NOV 21 A9:25

November 9, 2001

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

**Re: Docket No.01D-0220: Draft Guidance for Industry: Biological Product
Deviation Reporting for Blood and Plasma Establishments.**

Dear Docket Officer:

The San Diego Blood Bank would like to thank you for this opportunity to provide comments and/or questions regarding the draft guidance for industry concerning the Center for Biologics Evaluation and Research's draft guidance on biological product deviation reporting for blood and plasma establishments.

Section IV.A.1. Post Donation Information

Travel or living the UK. The draft guidance includes as an example of reportable post-donation information: "Donor spent 6 months or more in the United Kingdom from 1980 through 1996." We are seeking clarification to this statement. Are we required to report an event if the donor no longer has in-dated products available for recall? Should we always report if successful donations were made within the past year, or past 5 years?

Donor implicated in transfusion associated disease, unless donor is subsequently ruled out as the cause. Currently, there are no guidelines for reporting this type of incident. We do not understand the reasoning or value of reporting this incident to the FDA. It is not a deviation or unexpected event, in that all testing was negative for the implicated units. Additionally, hospitals report this type of event, even when the patient may have had the disease process before receiving blood. We would request that you reconsider including this type of incident as a biologic product deviation report.

Donor tested negative and products were distributed, and donor returns and subsequently tested positive for and viral marker. We respectfully request to delete this incident from the reporting requirement. Again, it is not an unexpected event, and all viral markers were negative at the time of the original donation. What is the reason for performing notification to the FDA? At a time when personnel resources are scarce, this seems to only create more reporting work, with no value added.

01D-0220

CS

Thank-you for this opportunity to comment on the “Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments”. If you have any questions, please feel free to contact me or the Director, Quality Assurance/Compliance, Ms. Patricia E. Bakke, by phone at (619) 296-6393, or by e-mail at rwalker@bloodbank.org or pbakke@bloodbank.org.

Sincerely,

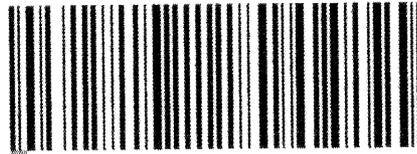
A handwritten signature in cursive script that reads "Ramona L. Walker". The signature is written in black ink and is positioned above the printed name and title.

Ramona L. Walker
Chief Executive Officer

**San Diego
Blood Bank**
A Regional Blood Center
440 Upas Street
San Diego, California 92103-4900



CERTIFIED MAIL



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