



OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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**The follow comments were submitted
on November 13 by e-mail to fdadockets@oc.fda.gov**

November 13, 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**Re: Docket No. 01D-0220: Draft Guidance for Industry: Biological Product Deviation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:

Thank you for the opportunity to provide comments and suggestions regarding the draft guidance for industry concerning the Center for **Biologics** Evaluation and Research's draft guidance on biological product deviation reporting for blood and plasma establishments.

The members of America's Blood Centers, who collect, process and distribute nearly half of the nation's blood supply for transfusion would like to bring the following to your attention:

Section IV.A.1.

Post Donation Information: Subpart 1 of Section IV of the guidance is not consistent with other descriptive subparts included in Section IV with respect to product status. Other sections clearly indicate, "A biological product deviation report is required when either of the following events occurs and the products are distributed." We recommend that this language be included in Section A,

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 The draft guidance includes as an example of reportable post-donation information: "Donor spent 6 months or more in the United Kingdom from 1980 through 1996."

Please clarify the reporting requirements in the situation where the donor's previous donation was so long ago that there are no in-date products, or products for further manufacturing that fall within the timelines as defined by plasma derivative manufacturers.

Donor implicated in transfusion associated disease, unless donor is subsequent & ruled out as the cause. Please clarify whether it is necessary to file a report when a center is notified that a donor may have a transfusion-associated disease, or after subsequent testing is done. We would like to point out that if it is necessary to call the donor in to obtain a sample and conduct follow-up testing, we may not receive the results within the 45-day reporting timeframe.

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Section I??

Retrieval, Consignee Notification and Lookback

We request clarification concerning the reportability of **Lookback** cases. Individual cases of **Lookback** have been the subject of FDA reporting in the event "the investigation reveals that the release of the implicated unit(s) was the result of an error or accident in manufacturing" (FDA Memorandum, *Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components*, March 20, 1991.) The focus of the reporting responsibilities were on the occurrence of an error/accident-not the underlying reason for the **lookback** case. However, this draft guidance states that FDA reporting is required based upon the determination that the blood product caused an adverse effect. This is a change in focus from the original reporting requirements, which focused on the occurrence of an error/accident.

If, in fact, **Lookback** reporting requirements are expanded, this is a significant change from the 1991 memorandum and should be included in the guidance Introduction (Section I) as a fifth bullet item. Please clarify the intent and rationale behind this change.

Donors at Increased Risk of CJD or vCJD. The reporting requirements for donors at increased risk for CJD or vCJD are confusing. We recommend that the guidance be revised to clarify whether it is necessary to quarantine and retrieve all products potentially affected, or only in-date products.

Section IV.E (Labeling). Among the examples for biological product deviations that should not be reported is: "Directed unit, suitable for allogeneic use, labeled with incorrect or missing donor information..."

We would like to point out that most directed units do not have donor information on the units, only the patient information. Was this intended to mean patient information? If so, we agree that incorrect patient information on directed units should not be reportable, since this does not affect safety, purity or potency of the unit. (All directed units must meet allogeneic standards.)

I would be glad to answer any questions you may have about ABC's comments.

Yours truly,



Heather Russell
Chair, Quality Committee
America's Blood Centers