

November 12, 2001

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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**Re: Docket No. 01D-0220: Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments.**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the opportunity to provide comments and suggestions concerning the Center for **Biologics** Evaluation and Research's draft guidance on biological product deviation reporting for blood and plasma establishments. We wish to bring the following to your attention.

**Section IV, A 1, Post Donation Information**

This section describes the following events as reportable: *Donor tested negative and products were distributed, the donor returns and subsequently tested positive for any viral marker and Post donation information also includes information that a blood center obtains when it adds new donor history questions. In response to a new question, donors may provide information that they did not provide at an earlier donation. If the additional information may affect the safety, purity, or potency of the product, you must file a report.*

Seroconversion for significant viral markers occurs on a routine basis during the course of normal donor screening and consignee notification is undertaken, as appropriate, in accordance with applicable FDA memoranda and guidance. Criteria for consignee notification are also addressed in new donor questions required by FDA. Are these events reportable only if prior testing is suspect or if the consignee notification described in FDA guidance has not been undertaken? Please clarify the intent and rationale behind the requirements in the **draft** guidance.

**Section IV. A. 2, Donor Screening and Deferral**

Item (iv), *Deferral procedures*, requires reporting when *incorrect donor identification information* is used to check the deferral list, regardless of whether the donor is deferred and even if the donor is the source of the discrepant information, i.e., variation in names on two different donations.

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Please clarify the intent and rationale behind this requirement. Computer systems in use at most blood centers have algorithms that permit the identification of deferred donors even if the incoming data provided by the donor is not an exact “match”. Reporting every event where the donor provides different information is a pointless exercise unless it results in the inappropriate release of products **from** a deferred individual.

**Section IV, F, Quality Control and Distribution**

This section describes reporting a distributed unit that is ***hemolyzed or with hemolyzed segments attached***. Please clarify these issues in the context of product control. Problems concerning hemolysis discovered by the consignee upon receipt of a product should be reported by the processing/distributing facility. Hemolysis discovered after the product has been under the custody and control of the receiving institution should be reported by the consignee.

In addition, this section describes as reportable ***Quality control or quality assurance procedures were not followed or not performed***, In the slide presentation displayed at the recent AABB Annual Meeting, ***Routine QC notperformed, QC before and after acceptable*** was described as non-reportable. Please clarify.

Sincerely,



Edwin W. Streun  
Director, Regulatory Affairs

cc: D. Kender, Ph.D.

NEW YORK BLOOD CENTER  
303 E 86TH ST STE 319  
NEW YORK NY 10021  
2125703285

SHIP DATE: 12NOV2001  
ACCOUNT # 010055580  
ACTUAL WGT: 1.00 LBS

TO:

DOCKETS MANAGEMENT BRANCH  
(HFA-305)  
FOOD & DRUG ADMINISTRATION  
5630 FISHERS LANE  
ROCKVILLE MD 20852

212-570-3000

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