



November 9, 2001

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Food and Drug Administration
5630 Fishers Lane, Room 106 I
Dockets Management Branch, HFA-305
Rockville, MD 20852

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (August 2001)," Docket No. 01D-0220

Dear Sir or Madam:

Nabi is pleased to provide these comments on the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (August 2001)." The Source Plasma industry recognizes the importance of monitoring Biological Product Deviation Reports (BPDR) and appreciates the Agency's assistance in defining the types of reports and the timeframe for reporting. However, industry is concerned regarding the increased reporting requirements. Clarification is being requested on the submission of BPDRs for subsequent positive tests for viral markers on a donor that previously tested negative, and new donor history questions.

Section IV (page 17) of the Draft Guidance includes the following in describing unforeseen or unexpected events:

"Other similar situations that would be reportable as an unforeseen or unexpected event that may affect the safety, purity or potency of previously distributed products may include...: Donor tested negative and products were distributed, the donor returns and subsequently tested positive for any viral marker."

A donor with a negative history who subsequently tests positive for a viral marker is not considered to be an "unexpected" or unforeseeable" event. Industry currently uses safety nets such as donor screening, the viral marker standard, PCR testing and inventory hold, to reduce the potential risk associated with this type of event. Adequate procedures such as **lookback** and inventory hold serve to protect public health. While we agree that the safety and purity of product collected before the positive test may be affected, we feel the industry has implemented effective procedures to mitigate the risk. Therefore, we request that FDA re-consider including this category for the submission of BPDRs and consider an alternative epidemiological data collection mechanism. The plasma industry, represented by **ABRA**, would be pleased to meet with FDA to discuss an alternate mechanism.

01D-0220

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Nabi also requests a clarification on the BPDR requirements when a new question is added to the donor history questionnaire as part of the donor screening process. The Draft Guidance entitled, "Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products (August 29, 2001)" recommends that Source Plasma centers include additional travel questions during the screening process. The guidance language implies that BPDRs will be required for donors that become deferred as a result of the new donor screening questions. This reporting requirement presents an increased burden for industry and represents reporting events that the agency knows will occur. Were donors not expected to be deferred by the new question, there would be no need to add the question to donor screening. Furthermore, individual reports are not an efficient means for reporting the impact of new screening questions. Nabi requests that FDA consider an alternate mechanism for the collection of these data.

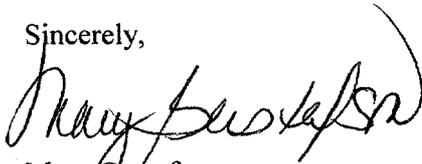
Furthermore, Section IV.A.2. (ii) states:

"A biological Product Deviation Report is required when any of the following events occur and products are distributed.. Donor's hemoglobin or hematocrit is unacceptable."

Errors resulting from obtaining the donor's hemoglobin or hematocrit for the collection of Source Plasma are a donor safety issue, not a product safety or quality issue. We request that this type of BPD be eliminated as a requirement for a reportable event.

Nabi appreciates the opportunity to comment on this Draft Guidance. Should you have any questions regarding these comments or would like additional information, please contact me at (561) 989-573 1. Thank you for your consideration.

Sincerely,



Mary Gustafson
Senior Director
Regulatory Affairs/Plasma

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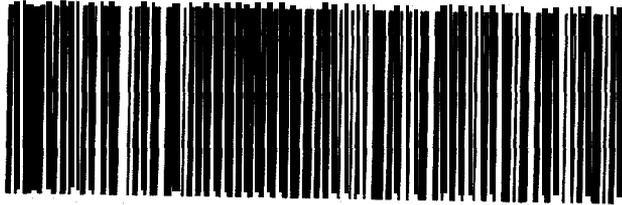
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