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October 25, 2001

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

RE: Reference Number FDAA01015

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant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 2001)," Docket Number 97D-0318

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Nabi is pleased to provide these comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant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 2001)," Docket Number 97D-0318.

General Comment: The guidance document is complex because the information is complex and evolving. Nevertheless, given the complex nature of the document, it is challenging for the reader to properly classify the donor and determine the appropriate actions for donor deferral, product retrieval, and reporting. Using one of several information-mapping techniques to improve document flow and provide traceability of recommended actions regarding the donor to the final product would enhance the guidance. One such example was a tabular format presented to agency personnel at the October 11, 2001, FDA/ABRA/PPTA liaison meeting.

Specific Comments:

1. Section IV.D. states three different time intervals for asking the recommended donor screening questions: Once, annually, and intervals not to exceed three months. These different intervals should be more visibly stratified in the document. Specifically, the need to ask questions 1 – 3 one time only is obscured by the sentence's location following the recommendation to question donors no less than every three months.

Regarding the recommendation for asking questions 4 and 5 every three months, we recognize the need for assessing current risk in the proposed Question 4 and the proposed Question 5. However, please consider recommending that Question 5 be asked at the annual physical for Source

97D-0318

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5800 Park of Commerce Blvd NW
Boca Raton, FL 33487
(561) 989-5800
Fax (561) 989-5801
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Plasma donors, and updated throughout the year as part of the current question that asks the donor about receiving blood within the past 12 months.

In addition, we recommend that you consider a different interval at which Source Plasma donors are asked Question 4. Three months is not an interval tracked for any purpose in plasma collections. In most cases, asking the question annually should be sufficient with an SOP directive to track independently the rare donor who presents with a French residency of 4 years or greater at an annual physical. If annually is not considered sufficient, we request the recommendation be revised to "no greater than four months" as part of the donor screening at the time of the four-month sampling. Source Plasma centers are currently tracking Serum Protein Electrophoresis (SPE) for the donors at four-month intervals. If these screening questions were asked annually or alternatively at four-month intervals, the tracking methods for the centers would be less cumbersome and adherence to the guidance would be improved.

2. Section IV.A. of the document states that Source Plasma establishments should "appropriately counsel" donors at an increased risk for CJD. We are requesting clarification on the expectation for appropriate counseling of donors for CJD and vCJD. Is notification of the deferral and reason for deferral sufficient?
3. Section V.A. discusses the recommendations for product retrieval and quarantine for blood and blood components, including Source Plasma. Previous guidance allowed an exception for lookbacks for the entire 10-year expiry for Source Plasma if a consignee acknowledges that any product shipped to it would be pooled within a shorter period of time. We recommend the addition of a similar exemption in this guidance. Because of the long expiration dating for Source Plasma and the relatively short time interval from collection to use, lookbacks become laborious administrative tasks with little value in retrieving extant product.
4. Section V.C. states that the FDA notification is required as soon as possible, and a telephone number is provided. We are requesting clarification as to whether a Biological Product Deviation Report (BPDR) suffices as notification to FDA, or if in addition to the BPDR, manufacturers are requested to notify the FDA via telephone or official written correspondence. Prior guidance documents had recommended that the blood establishment report these cases both to the FDA and the CDC, and we request clarification as to whether CDC should be notified as well. If FDA wishes reporting beyond the reporting required by the regulations, it is confusing to the reader to tie the requests together under the umbrella of regulations that are only partially applicable.

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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. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Gustafson". The signature is fluid and cursive, with a large initial "M" and "G".

Mary Gustafson
Senior Director
Regulatory Affairs/Plasma

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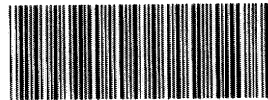
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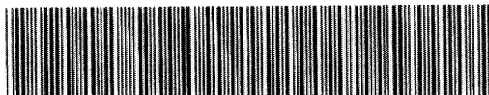


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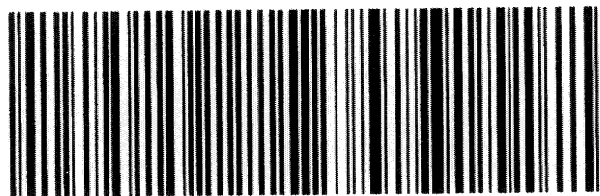
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