



Blood Systems, Inc.

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September 26, 2001

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

Re: Docket No. 97D-0318
Guidance for Industry
Revised Preventive Measures to Reduce the Possible Risk of Transmission of
Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood
and Blood Products.

To Whom it May Concern:

Blood Systems, Inc. is pleased to have the opportunity to comment on the Center for Biologics Evaluation and Research's draft guidance document of August 2001.

Section IV.B.

The guidance document states that whole blood donors should be asked questions 1, 2 and 3 at each donation to identify donors at an increased risk for CJD.

We recommend that the guidance document exempts establishments with approved abbreviated donor screening methods, administered to frequent repeat donors (FRD), from the above requirements when pertinent information can be captured through other questions.

For example, a FRD who denied history of CJD at prior donations, is expected to answer positively had he developed CJD since his last donation when asked: "Since your last blood donation, have you had any new medical conditions or health problems?" The same question will identify donors who have had a medical condition requiring treatment with dura matter.

Section IV.D.

We suggest that FDA consider limiting Phase I deferrals to cumulative time spent in U.K., deferral for military personnel, civilian military personnel, and their dependents, and for recipients of transfusion in the U.K.

Section IV.D.

Similar to Section IV.B, above, the guidance document states that whole blood donors should be questioned at each donation to identify those at increased risk for exposure to BSE. However, the guidance allow blood establishments to ask donors once, for questions 1-3 in Phase I, because these deferral questions encompass a discrete time frame.

We recommend that the guidance document exempts establishments with approved abbreviated donor screening methods, administered to frequent repeat donors, from the above requirements when pertinent information can be captured through other questions.

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For example, an eligible FRD who has not been outside the United States or Canada since his last blood donation would be expected to answer negatively to question 4 and 5 in section IV.D.

In addition we enclose an alternative donor screening algorithm as part of the Uniform Donor Health Questionnaire (UDHQ) for your consideration (Attachment 1). Attachment 2 demonstrates the feasibility of the Abbreviated Donor Health Questionnaire in identifying donors at risk for exposure to BSE.


Section IV.D. Question 1):

It is noted that Gibraltar and the Falkland Islands have been added to the United Kingdom territories with geographic risk of BSE exposure.

We request that the final guidance document address the geographic risk of BSE exposure in the following UK territories: Bermuda, British Virgin Islands, Anguilla, Cayman Islands, Turks and Caicos Islands, Pitcairn Island and Saint Helena Island. This assumes that as British territories their primary source of beef comes from imports, restricted in source to the U.K.

Thank you for the opportunity to comment. If you have any questions, please contact me at (480) 675-5458.

Yours truly,



Thomas B. Wiltbank, M.D.
Corporate Medical Director

ATTACHMENT 1
Donor Screening Questions Alternative to those listed in Section IV.D.
To identify donors at increased risk for exposure to BSE

Phase I.

1. **Since 1980, have you spent a total of 3 months or more in Europe?**
If NO, go to question # 2
If YES:
 - A. Since 1980, have you spent a total time of 5 years or more in France?
 - B. Since 1980, have you received a transfusion of blood, platelets, or plasma in the United Kingdom?
 - C. From 1980 through 1996, have you spent a total time of **three months** or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)?
 - D. From 1980 through 1996, have you spent a total time of **6 months** or more on a military base in Europe?
If NO, go to question # 2
If YES:
 - E. Between 1980 and 1990, have you been stationed in Belgium, the Netherlands, or Germany, for **6 months** or more?
 - F. Between 1980 and 1996, have you been stationed in Spain, Portugal, Italy, Turkey, or Greece for **6 months** or more?
2. **Since 1980, have you at any time injected bovine (beef) insulin?**

Phase II.

1. **Since 1980, have you spent a total of 3 months or more in Europe?**
If NO, go to question # 2
If YES:
 - A. Since 1980, have you spent a total time of 5 years or more in **BSE risk countries of Europe**?
 - B. Since 1980, have you received a transfusion of blood, platelets, or plasma in the United Kingdom?
 - C. From 1980 through 1996, have you spent a total time of three months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)?
 - D. From 1980 through 1996, have you spent a total time of six months or more on a military base in Europe?
If NO, go to question # 2
If YES:
 - E. Between 1980 and 1990, have you been stationed in Belgium, the Netherlands, or Germany, for 6 months or more?
 - F. Between 1980 and 1996, have you been stationed in Spain, Portugal, Italy, Turkey, or Greece for 6 months or more?
2. **Since 1980, have you at any time injected bovine (beef) insulin?**

ATTACHMENT 2
Demonstration of the screening of the Frequent Repeat Donor (FRD)
using an Abbreviated Donor Health Questionnaire

Uniform Donor Health Questionnaire (UDHQ)	Abbreviated Donor Health Questionnaire (ADHQ)
Administered to: First time donors Repeat donors ineligible for ADHQ FRD eligible for ADHQ (One time after implementation of the updated UDHQ)	Administered to FRD eligible for ADHQ <u>only</u> after completing the updated UDHQ at least once.
<p>1. Since 1980, have you spent a total of 3 months or more in Europe? If NO, go to question # 2 IF YES:</p> <ul style="list-style-type: none"> a. Since 1980, have you spent a total time of 5 years or more in France (Phase I) or BSE risk countries of Europe (Phase II)? b. Since 1980, have you received a transfusion of blood, platelets, or plasma in the United Kingdom? c. From 1980 through 1996, have you spent a total time of three months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)? d. From 1980 through 1996, have you spent a total time of six months or more on a military base in Europe? IF NO, go to question # 2 IF YES: <ul style="list-style-type: none"> e. Between 1980 and 1990, have you been stationed in Belgium, the Netherlands, or Germany, for 6 months or more? f. Between 1980 and 1996, have you been stationed in Spain, Portugal, Italy, Turkey, or Greece for 6 months or more? <p>2. Since 1980, have you at any time injected bovine (beef) insulin?</p>	<p>Since your last blood donation: Have you been outside the United States or Canada? If YES, ask follow-up questions: Where, When, and How long did you stay? <u>EVALUATE DONOR FOR:</u> vCJD risk</p> <ul style="list-style-type: none"> 1. Have you been to Europe? IF YES: <ul style="list-style-type: none"> A. Since 1980, have you spent a total time of 5 years or more in France (Phase I) or BSE risk countries of Europe (Phase II)? B. Have you received a transfusion of blood, platelets, or plasma in the United Kingdom?

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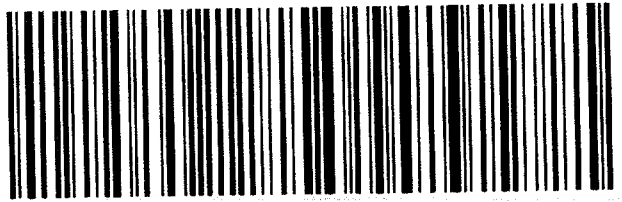
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