America's Blood Centers

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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

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 Draft Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease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

Dear Docket Officer:

Thank you for this opportunity to provide comments and suggestions regarding the draft guidance for industry concerning revised measures to decrease the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and variant CJD (vCJD).

Members of America's Blood Centers wish to bring the following to your attention:

Introduction. The draft guidance states that CJD guidance regarding iatrogenic, familial, and sporadic disease remains unchanged. In fact, however, there are changes, *e.g.*, "reentry" of donors with familial CJD. We recommend that the Center for Biologics Evaluation and Research (CBER) state that this current guidance supercedes prior memos and documents on both CJD and vCJD.

Section II. Background. FDA states that "we changed the 1996 recommendation to withdraw plasma derivatives from donors with CJD or CJD risk because of recently published epidemiological and laboratory data which provided additional assurance that *the transmission of CJD by blood and blood products is unlikely*" (paragraph 8, emphasis added). In light of no further evidence to the contrary, we ask CBER to discontinue recommendations to retrieve/quarantine/destroy all in-date transfusable products from these donors and to discontinue the tracing and notification of recipients as outlined in Section VI.

Section III. B. Exposure to British Beef Products Distributed Outside of the UK.

The following sentence in the last paragraph is unclear: "Due to the potential exposure to U.K. beef on U.S. military bases in Europe, we recommend that you should indefinitely defer current and former military personnel, civilian military employees, and their dependents who were stationed at European bases for 6 months or more during the time periods outlined above." This could be interpreted as increasing the scope of at-risk individuals to include all current and former U.S. military personnel. We recommend revising this statement as follows:

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> Due to the potential exposure to U.K. beef on U.S. military bases in Europe, we recommend that you should indefinitely defer the following individuals who were stationed at European bases for 6 months or more during the time periods outlined above: Current and former U.S. military personnel and dependents, civilian military employees and dependents

In addition, please define the group "civilian military personnel" in this section.

Section IV. D. Paragraph 1. Recommended Questions for Identifying Donors at Risk for Exposure to BSE. ABC members are consistently concerned that the questions are too long and complex to expect appropriate donor comprehension during an oral, face to face interview. Furthermore, CBER has given no rationale for why the questions should be asked orally. We recommend three alternatives:

1. The donor could read the circumstances that confer a geographic risk of BSE exposure and then respond to a simple question as to whether any of the risks apply;

2. The donor could complete a written travel log followed by evaluation of the log by trained collection personnel, or

3. A broad screening question such as "Have you traveled outside the US or Canada since 1980?" followed by more detailed interview of donors responding in the affirmative.

We believe that these alternative approaches are especially important since donor history cards, in their current format, will not accommodate the five additional recommended questions in a readable font size.

Section IV. D. Paragraph 2. Please consider listing countries in Europe, between 1980 and the present, which are not at risk of BSE.

Consider including in the document an explanation in plain language for donors who ask for rationale explaining why they are deferred from whole blood donation but are acceptable for source plasma donation.

Section IV. D. Paragraph three. Please clarify the apparent contradiction between the requirements to question whole blood donors "at each donation" (line 2), but subsequently only "once" (line 3).

Section IV.D. (1) To identify donors with geographic risk of BSE exposure: Phase I: Question 1. Inclusion of "Gibraltar and the Falkland Islands", in parenthesis after "United Kingdom" implies, erroneously, that they are part of the United Kingdom (when, in fact, they are part of the British Commonwealth).

Question 5 (Have you received a transfusion of blood, platelets, or plasma in the United Kingdom . . .") does not include cryoprecipitate. Is it CBER's intention to exclude this component from the question?

Appendix. 9 CFR 94.18, the citation for countries with BSE risk, lists Oman as having BSE yet this country is not in the draft guidance nor would it be detected via the European exclusion. Please explain the rationale for this exclusion.

Section V. A. and B. Recommendations for Product Retrieval and Quarantine. Please clarify whether "in date" in section A is equivalent to "implicated" in section B.

Section VIII. Implementation of Recommendations. We strongly recommend a single implementation date, October 31, 2002. ABC member centers have expressed considerable concern about the complexity that two implementation dates introduces. A single implementation date in October 2002 would ensure that education, for donors and blood center staff, training, literature, donor registration cards, and standard operating procedures would not have to be revised twice within a short period of time.

General Comments. The document refers repeatedly to whole blood donors, but, presumably, apheresis donors of platelets, double red cells and source plasma are also to be included. Please clarify this.

Thank you for the opportunity to comment. If you have any questions, please feel free to contact me.

Yours truly,

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