

October 10, 2001

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Re: Docket No.97D-0318 - Draft Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease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

The American Association of Blood Banks (AABB) task force on the Circular of Information for the Use of Blood and Blood Components is composed of representatives of the blood community, including AABB and America's Blood Centers (ABC). The task force prepared the most recent version of the Circular and is currently drafting the next version. This Circular is used by the entire blood banking community.

The task force appreciates the opportunity to comment on the labeling proposal in Section VII B of the 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." The guidance states that the labeling to address the theoretical risk of transmission of CJD and vCJD for whole blood and blood components intended for transfusion should appear in the Circular under "Side Effects and Hazards." The following language appears in the current Circular (August 2000) under "Notice to All Users". *"WARNING: Because whole blood and blood components are made from human blood, they may carry a risk of transmitting infectious agents, eg viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent."* The task force believes that this language meets the intent of the draft guidance. Because the draft guidance makes a clear distinction between CJD and vCJD, the task force believes that both CJD and vCJD should be mentioned in the warning. We suggest the following wording:

"WARNING: Because whole blood and blood components are made from human blood, they may carry a risk of transmitting infectious agents, eg viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent and variant Creutzfeldt-Jakob disease (vCJD) agent."

97D-0318

C 25

Since the risk of CJD and vCJD transmission by blood transfusion is considered to be theoretical, the task force believes that it is more appropriate to place the warning in the section titled "Notice to all Users."

The task force requests that the guidance be changed to use the language in the current Circular as modified above, and to place that language in the section of the Circular titled "Notice to all Users."

Sincerely,

Karen Cipolone (atu)

Karen Cipolone, MT(ASCP)SBB, CQA(ASQ)
Chair
AABB Circular of Information Task Force