

8012 '01 SEP 21 P4:13

September 21, 2001

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Re: Docket No. 97D-0318: Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD)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 (*Federal Register*, Vol. 66, No. 168, August 29, 2001, p. 45683)

On behalf of the American Association of Blood Banks (AABB), I am requesting an extension until October 12, 2001, of the September 28 deadline for comments on the Food and Drug Administration's above-referenced draft guidance on additional measures to reduce the possible transmission of Creutzfeldt-Jakob disease and variant Creutzfeldt-Jakob disease.

Due to the extraordinary events of the last week and the continued stress on the nation's blood collection system as a result of the terrorist attacks on New York City and Washington, DC, AABB regulatory affairs staff have been unable to focus our attention on providing comments on this new donor deferral policy. Since this new donor deferral policy will have a major impact on blood center operations and on the blood supply as a whole, we believe that it is necessary that we provide careful and detailed comments to the Center for Biologics Evaluation and Research.

We request a two-week extension of the comment period (until October 12) to provide us with the time to prepare and submit our comments.

Sincerely,

Kay R. Gregory (atw)

Kay R. Gregory, MS, MT(ASCP)SBB
Director
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97D-0318

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