



OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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March 30, 2000

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

Re: Docket No. 99D-5046: Draft Guidance for Industry; Changes to an Approved Application:  
Biological Products: Human Blood and Blood Components Intended for Transfusion or for  
Further Manufacture

To Whom it May Concern:

America's Blood Centers is pleased for the opportunity to comment on the Center for Biologics Evaluation and Research's draft guidance on changes to approved applications for blood and blood components for transfusion or further manufacture. We thank CBER for providing guidance in this area that is specific to blood and blood components. In general, the draft guidance is well-written and easy to understand. In this regard, the Definitions section is very useful, and has new wording that further clarifies the terms. We also appreciate the inclusion of a sample format for the Annual Report, which should help our members provide the information that CBER is seeking.

Our specific comments follow.

**SCOPE:**

Please clarify whether or not changes that affect unlicensed products need to be reported to FDA at all. This draft appears to imply that all blood and blood components are licensed. However that is not the case for many blood establishments.

**DEFINITIONS:**

**Transfusion Services.** Please note that some blood centers provide outpatient health care that includes transfusions. This activity is not exclusive to hospitals.

99D-5046

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**Definitions (continued):**

**Distribution Centers.** Please clarify the definition of a "Distribution Center." Would a hospital transfusion service be required to be listed as a distribution center if they transfer fully processed-blood components drawn and processed by the blood center to another transfusion center? For example, if hospital A had units of blood on their shelves from the blood center, and hospital B had an urgent need for the same units, and the blood center made arrangements for the units to be transferred from hospital A to hospital B, would this qualify hospital A as a distribution center? a contractor? or is it exempted as prescribed in 21 CFR 607.65 (f)?

**Section III. A. 2. (Changes under 21 CFR 601.12(b), NOTES).** Please clarify what is meant by "post-approval FDA inspections." Is a "pre-license FDA inspection" the same as a "pre-approval FDA inspection?"

**Section III. B. 2 (Equipment Changes).** We recommend that changes to the process to decrease donation time and increase product yield above minimum FDA specifications, or COBE LRS v 5.1 to Turbo v.7 not be PAS. The equipment or upgrades here have already been 510(k) reviewed and all these process changes will be validated in-house to ensure process controls are adequate, and anticipated outcomes are met.

**Section IV. A. 1 (Product Manufacturing/Procedural Changes under 21 CFR 601.12(c).** We question the need for CBE30 for more restrictive SOPs than FDA requires. Such a change is above and beyond the minimum set by FDA, and should not be under CBE30 level reporting.

**Section IV. B. 1 (Equipment Changes under 21 CFR 601.12(c).** It seems inconsistent that a manufacturer's equipment change is CBE30, but a manufacturer's software upgrade, or COBE LRS v 5.1 to Turbo v. 7 is PAS. We recommend that both be CBE30, since the manufacturer has submitted a 510(k) on these changes, and changes will be validated in-house.

**Section VI. A. 2 (Product Manufacturing/Procedural Changes under 21 CFR 601.12(d).** We do not believe that a SOP describing the use of an FDA-approved AABB Uniform Donor History Questionnaire should require PAS or CBE30. This process will be validated in-house; moreover, FDA already has approved the questions.

**Section VI. A. 5.** ABC believes that SOPs or tests implemented by a manufacturer that are not required by CBER should not be subject to annual reporting, since they do not affect CBER's requirements on approved applications.

Thank you for the opportunity to comment. If you would like to discuss the above questions further, I can be reached at (302) 737-8405, ext. 767.

Yours truly,



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Chair, Quality Committee, America's Blood Centers



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