Blood Systems, Inc.

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

Gentlemen:

Thank you for the opportunity to comment on the Proposed Guidelines on cGMP for Blood and Blood Components (1) Quarantine and Disposition of prior collections from donors with repeatedly reactive screening tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).

Listed below are our (Blood Systems, Blood Centers of the Pacific, and Tri-Counties Blood Bank) observations on the recent FDA revised Draft HCV 1.0 Lookback guidelines.

Section II Search Period (Page 5-last paragraph and elsewhere).

The period of record review has been extended beyond the previous recommendation to require retrospective review for an indefinite period with the proviso that this be limited "to the extent that electronic or other readily retrievable records exist". The current regulations already allow for a greater than 10 year period of record review in that those refer back to January 1, 1988, while these new regulations propose an extension that goes even further beyond current industry practice.

The current proposals are of concern because :

- they extend record review beyond industry practice and could have the effect of creating a new industry-wide standard without the usual cost impact analysis
- the majority of hospitals will not have records beyond 5 years or beyond the period previously identified in regulations of this type
- they are inconsistent with the standards going forward that are proposed herein
- the inevitable inconsistent responses by blood centers and hospitals needlessly exposes both to litigation through creation of a standard that cannot now be achieved.

It is proposed that the time period of retrospective review be restricted to January 1, 1998 or to a 10 year time period. As a matter of practice, almost no hospitals within the

Blood Systems service area have patient records adequate to support retrospective review much before 1990.

Section III 3 A. Review of Records (Page 17, first paragraph & elsewhere).

Based on current dating limitations, only Frozen Red Cells fall within the scope of "in date" prior donation products. Studies of United Blood Services donors have revealed that attempts to recall 7800 donors for repeat testing resulted in a response rate of 12% or less with the result that it is, for all practical purposes, impossible to retest these donors to make determinations about the acceptability of in date products. Since the period of use of HCV 1.0 was comparatively short, many years ago, and only a small number of products will be in date, it seems unreasonable to require record review within 3 days of test identification. It is suggested that this be changed to "promptly" or alternatively "within a reasonable period of time".

Section III 3 C Paragraph 2 Release from Quarantine.

Similarly, it is unreasonable to expect that the status of those products be resolved within 45 days after such a long delay. It is suggested that this period be extended to 90 days.

Section III 3 B (ii) Resolution of HCV EIA 1.0 Test Results.

The proposed regulations require that RIBA 3.0 be used to confirm whether EIA 1.0 repeat reactive samples with an S/CO ratio of greater than 2.5 should initiate lookback procedures. It is not clear why this section requires direct use of RIBA 3.0 rather than use of EIA 3.0 followed by RIBA as described in Section II 2 E 1 (ii). This alternative approach would be less expensive and allow more rapid reconciliation of the question. It is proposed that this be applied to EIA 1.0 sample reconciliation.

I hope these observations are of assistance and will be taken into consideration in the final version of the regulations.

Yours sincerely

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