San Diego
Blood Bank
A Regional Blood Center

February 7, 2001

Dockets Management Branch (HFA 305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket No 99N-2337:Proposed Rule: Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ("Lookback") [Federal Register: November 16, 2000 (Volume 65, Number 222)].

To Whom it May Concern:

San Diego Blood Bank (SDBB) appreciates the opportunity to comment on the new proposed HCV lookback regulations as outlined in the November 16, 2000 Federal Register. We seek clarification and offer requested input for the following:

610.46(a) (1) states that ""for blood and blood components collected from that donor at any time prior to the repeatedly reactive test, whenever records are available, if intended for transfusion or for further manufacturer into injectable products.....identify the prior collections from that and (i) quarantine all such prior collections of blood and blood components"...

1. This regulation refers to lookback for HIV. Does this mean that records must be searched indefinitely for both transfusable components and for recovered plasma for further manufacture? Plasma never outdates, so it is conceivable, to follow this regulation, we would have to search records that are 20 or 30 years old, and not readily retrievable. We suggest that a timeframe be identified, no more than 10 years for transfusable products and 6 months for recovered plasma for further manufacture.
2. Is the search confined to computerized electronic records? Please add wording to limit the search to computerized electronic records as you have for retrospective HCV lookback.
3. Is it confined to **in-date** records as is 610.48(a) for HCV lookback? Please clarify.

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610.46(a)(1) and 610.48(a)(1) states that ...the blood establishment shall, within 3 calendar days after the date on which the tested repeatedly reactive (ii) notify all consignees of the repeatedly reactive (HIV) HCV screening test result so that the consignee may quarantine all such prior collections of blood and blood components. If the blood establishment has to perform indefinite lookback, 3 calendar days is not ample time to perform identification, quarantine and notification. 7 calendar days or 5 business days is a more appropriate time fame.

610.48(d)(3-4) describes the review of historical testing records and identification of donors tested using a single antigen-screening test prior to the effective date of final rule (third and fourth instances). Our prior understanding was that with signal to cutoff (S/CO) ratios less than 2.5 on a single antigen assay, there would be no consignee notification or lookback. The provisions in (3) (third instance) conflict directly with this understanding, and would require that blood establishments identify previously distributed blood and blood components from such donors when any single antigen test was repeat and there is no record of a supplemental test or multi-antigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor. The whole point of the use of S/CO was to minimize the need for consignee notification and lookback or recall for further phlebotomy of a large population of probable false positives with no supplemental results on record. 610.48(d)(3), and further similar references must be deleted.

The San Diego Blood Bank appreciates this opportunity to comment on the Draft Rules, and encourages FDA to evaluate this issue carefully.

Sincerely

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