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ABRA

The International Authority for the Source Plasma Collection Industry

147 Old Solomon's Island Road · Suite 100 · Annapolis MD 21401
Tel: 410.263.8296 · Fax: 410.263.2298
http://www.plasmainfo.org

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Reference No. FDAA01003

BY HAND DELIVERY

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

SUBJECT: 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")*, Docket No. 99N-2337

Dear Sir or Madam:

ABRA is pleased to provide these comments on the Food and Drug Administration's (FDA's) recently published proposed rule entitled, *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")* ("Proposed Rule"), 65 Fed.Reg. 69378 (Nov. 16, 2000). ABRA is the trade association and standards-setting organization for the Source Plasma collection industry. ABRA represents the interests of approximately 400 plasma collection centers nationwide. These centers are responsible for the collection of nearly 11 million liters of Source Plasma annually. This plasma makes up roughly 60% of the world's plasma supply and is manufactured into life-supporting and life-sustaining therapies.

As agency officials have recognized, the nation's supply of blood and blood products is safer than it has ever been. Nonetheless, industry, FDA and the consuming public must be ever vigilant to protect the safety of the blood supply. Accordingly, ABRA supports the Agency's efforts to ensure that information is provided to consignees and to prior recipients of blood and blood components from a donor whose subsequent donation tests positive for antibody to hepatitis C virus (HCV) or otherwise is determined to have been at increased risk of transmitting HCV.

It is essential, however, that the Agency make clear *in the body of the final regulation* that although the lookback requirements set forth in Proposed

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Rule apply generally to both blood and plasma establishments, neither historic records review nor recipient notification are required for Source Plasma or Recovered Plasma that has already been pooled for further processing. The failure to clarify this point in the text of the regulation to be codified in the Code of Federal Regulations may result in industry and public confusion regarding the applicability of the lookback requirements to the Source Plasma and Recovered Plasma industries.

In the preamble to the Proposed Rule, FDA clearly and appropriately acknowledges this limitation on the applicability of the lookback requirements to the Source Plasma industry: "The proposal would not require quarantine of products that have already been pooled for further processing because the process of fractionation inactivates or removes the HCV." 65 Fed. Reg. at 69382. *See also* 65 Fed.Reg. at 69394 ("Plasma centers will be affected by the proposed rule only to the extent that these establishments store and distribute unpooled units to consignees that also retain unpooled units in their inventories.

For the purpose of this analysis, FDA has assumed that most [plasma] units will be pooled prior to the initiation of any 'lookback' activity and, therefore, that plasma establishments will be minimally affected by the proposed rule. Plasma establishments similarly will not be affected by the proposed requirements for review of historical testing records").

Furthermore, the FDA and the General Accounting Office have both consistently taken the position that pooled plasma, because of the viral removal and inactivation procedures used in manufacturing, does not present a meaningful risk of transmission of viruses such as HCV. *See, e.g.*, Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; Proposed Rule, 64 Fed.Reg. 45339, 45352 (Aug. 19, 1999); Blood Plasma Safety – Plasma Product Risks and Manufacturers' Compliance, GAO Testimony before the Subcmte. on Human Resources, Cmte. on Gov't Reform and Oversight, H.R. (Sept. 9, 1998) ("Proper viral inactivation and removal steps have resulted in no documented cases of HIV, HCV, or HBV transmission from plasma products since 1988").

As FDA already has explained the applicability of the lookback requirements to the Source Plasma industry in the preamble to the Proposed Rule, it behooves the Agency to make this information accessible in the Code of Federal Regulations in order to avoid any potential for confusion. ABRA therefore requests that FDA revise the lookback regulations to add a statement similar to the following: "Due to viral inactivation procedures during fractionation, the requirements pertaining to review of historical testing records and consignee notification set forth in § 610.48 are not applicable to pooled plasma."

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ABRA appreciates the opportunity to comment on this rulemaking. Should you have any questions regarding these comments or would like additional information, please contact me. Thank you in advance for your consideration.

Respectfully Submitted,

Christopher P. Healey
President, ABRA

CPH/mrs