Date: May 16, 1996

From: Director, Center for Biologics Evaluation and Research

Subject: Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)

To: All Registered Blood and Plasma Establishments

On April 23, 1992, August 5, 1993, and August 19, 1993, FDA issued memoranda to all registered blood and plasma establishments, which provided recommendations for testing for antibody to Hepatitis C Virus Encoded Antigen (anti-HCV). This memorandum supplements those previous memoranda by transmitting additional recommendations for testing for antibody to anti-HCV in blood establishments. (See attached recommendations.)

In a public meeting of the Blood Products Advisory Committee (BPAC) on March 21, 1996, after review and discussion of the relevant information available, concern was expressed that the use of a supplemental test for anti-HCV that uses fewer antigens than the screening test for anti-HCV may cause uncertainties. In particular, the Committee discussed its concern that the use of the Chiron RIBA HCV 2.0 Immunoblot Assay (SIA) as a supplemental test for anti-HCV should not be used for donor re-entry if the Ortho™ HCV Version 3.0 ELISA Test System was used as a screening test. FDA has considered the BPAC concerns and sets forth in the attached rcommendations donor re-entry and counseling procedures that should be used in this situation.

According to the attached recommendations, the use of either the Abbott HCV EIA 2.0 or the Ortho™ HCV 2.0 ELISA Test System to screen donor blood remains acceptable and no changes or clarifications to previous FDA HCV recommendation memoranda are needed. The Chiron RIBA 2.0 SIA would continue to be used as a supplemental test for both donor counseling and re-entry following screening with the latter assays.

Although this guidance document does not create or confer any rights, privileges or benefits for or on any person, and does not operate to bind FDA or the public, it does represent the agency's current thinking with regard to determining donor re-entry for donors who test repeatedly reactive when using the Ortho™ HCV Version 3.0 ELISA Test System.

Questions or comments concerning these recommendations may be directed to the Laboratory of Hepatitis, Division of Transfusion Transmitted Diseases, FDA/CBER, (HFM-325), 1401 Rockville Pike, Rockville, MD 20852; Phone: (301) 827-3011; FAX: (301) 496-0338.

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Attachment: Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)

Additional Recommendations for Testing for
Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)
In Blood Establishments

May 16 , 1996

On April 23, 1992, August 5, 1993, and August 19, 1993, FDA issued memoranda to all registered blood and plasma establishments, which provided recommendations for testing for anti-HCV. Additional recommendations are listed below.

1. The use of either the Abbott HCV EIA 2.0 or the Ortho™ HCV 2.0 Elisa Test System to screen donor blood remains acceptable and no changes or clarifications to previous FDA HCV recommendation memoranda are needed. The Chiron RIBA HCV 2.0 SIA would continue to be used as the supplemental test for these screening tests.

2. When testing donor blood, the same version of the HCV screening test, e.g., either 2.0 or 3.0, should be used for all initial and duplicate repeat tests.

3. For the purpose of determining re-entry to the donor pool, donors who test repeatedly reactive using the Ortho™ HCV Version 3.0 ELISA Test System may not be reinstated as suitable donors using the Chiron RIBA HCV 2.0 SIA as a supplemental test. Such donors should be temporarily deferred pending the availability of a licensed supplemental test containing the NS5 antigen.

   The reason for this recommendation is that the Ortho™ HCV Version 3.0 ELISA Test System contains an antigen, NS5, which is not part of the Chiron RIBA 2.0 SIA design. Therefore, until a supplemental test is licensed that includes the NS5 antigen, re-entry is not recommended.

   It is recommended, however, that samples from donors who test repeatedly reactive with the Ortho™ HCV 3.0 Version ELISA Test System be stored at -20^{o}C or colder until a suitable Licensed supplemental test is available.

4. For purposes of donor counseling and as a aid in diagnosis, donors who test repeatedly reactive using Ortho™ HCV Version 3.0 ELISA Test System may be tested using the Chiron RIBA 2.0 SIA. However, caution should be exercised when a negative Chiron RIBA 2.0 SIA test result is obtained because this supplemental test does not detect antibodies to the NS5 region.

5. FDA will notify blood establishments should a supplemental test become available that is suitable in all cases for the evaluation of donors who test repeatedly reactive using the Ortho™ HCV Version 3.0 ELISA Test System.