Disp. of blood for autologous use - reactive for Anti-HCV

Date: September 11, 1991

From: Acting Director, Center for Biologics Evaluation and Research

Subject: Disposition of Blood Products Intended for Autologous - Use That Test Repeatedly Reactive for Anti-HCV

To: All Registered Blood Establishments

This clarification responds to numerous questions that have arisen concerning FDA's recommendation for handling autologous blood products collected from anti-HCV reactive donors. FDA believes that public health considerations dictate the need for caution in the distribution and autologous use of anti-HCV reactive products. Accordingly, when the test for anti-HCV is repeatedly reactive, the blood product should be permanently labeled with the "Autologous use only" and special BIOHAZARD labels described in the current Guideline for the Uniform Labeling of Blood and Blood Components. The Circular of Information distributed with blood products should include appropriate explanation concerning use of the biohazard label when an autologous unit tests repeatedly reactive for anti-HCV.

Currently available screening tests for anti-HCV may be falsely positive, and FDA licensed more specific tests are not yet available. Additionally, the available tests may fail to detect HCV infection in a significant proportion of cases. It is appropriate, therefore, to make autologous units available regardless of the anti-HCV test results. The patient's physician should be informed of the repeatedly reactive test results, but it is not necessary to obtain written documentation of the physician's concurrence as outlined in the FDA's memorandum of March 15, 1989, for autologous use of HBsAg reactive or anti HIV-1 positive blood products. Autologous donors with repeatedly reactive screening tests for anti-HCV should be indefinitely deferred from donating blood for homologous use. In addition, autologous donors testing repeatedly reactive for anti-HIV-1, HBsAg, or anti-HTLV-I, should be deferred from donating blood for homologous use, unless and until the donors are reentered consistent with the guidance in FDA memoranda of 2 December 1987 (HBsAg), 29 November 1988 (anti HTLV-I), and 5 February 1990 and 5 December 1990 (anti-HIV-1).

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