

**Docket No. 2005D-0261**

**TABS 1-13**

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6. FDA Memorandum to All Registered Blood and Plasma Establishments: "Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen," August 8, 1995.
7. FDA Memorandum to All Registered Blood Establishments: "Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)," August 5, 1993.
8. Federal Register, 11/16/00 (65 FR 69378), 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")
9. Federal Register, 12/14/99 (64 FR 71147), Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2, December 1999.
10. Blood Products Advisory Committee, 69th Meeting, June 14, 2001, <http://www.fda.gov/ohrms/dockets/ac/cber01.htm>-Blood Products Advisory Committee.
11. Alter HJ. To C or not to C: These are the questions. *Blood* 85:1681-1695 (1995).

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12. CDC, Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR* 47, (RR-19) (1998).

13. See 21 CFR 610.40(b) for licensed test kits or 21 CFR 601.20(a) for licensed in-house assays.