Submission." The notice published with an inadvertent error in the **ADDRESSES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20957, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 2010–9134, appearing on page 20606, in the **Federal Register** of Tuesday, April 20, 2010, the following correction is made:

1. On page 20606, in the second column, in the **ADDRESSES** section, the second sentence is corrected to read: "Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent."

Dated: April 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10160 Filed 4–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0263]

Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)," dated May 2010. The guidance document provides recommendations to establishments that collect Whole Blood or blood components intended for transfusion, with recommendations for a requalification method or process for reentering deferred donors into the donor pool based on a determination that previous tests that were repeatedly reactive for antibodies to hepatitis B core antigen (anti-HBc) were falsely positive and that there is no evidence of infection with hepatitis B virus (HBV). These recommendations are based on the recent availability of FDA-licensed hepatitis B virus nucleic acid tests (HBV NAT) that are particularly sensitive when single samples are tested. These tests provide an additional, powerful method of determining whether a donor who has been deferred because of anti-HBc reactivity is truly infected by HBV. The guidance announced in this notice finalizes the draft guidance of the same title dated May 2008.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)," dated May 2010. The guidance document provides recommendations to establishments that collect Whole Blood or blood components for a requalification method or process for the reentry of deferred donors into the donor pool based on a determination that previous tests that were repeatedly reactive for anti-HBc were falsely positive and that there is no evidence of infection with HBV. Currently, donors who are repeatedly reactive on more than one occasion for anti-HBc (samples from more than one collection from the donor are repeatedly reactive for anti-HBc) must be indefinitely deferred in accordance with current regulations. Situations have occurred with some frequency in which two anti-HBc tests are false positives because of the relative non-specificity of these tests. The result is that many otherwise suitable donors are indefinitely deferred because of their anti-HBc test results even though medical follow-up of such donors indicates that they are not infected with HBV. FDA-licensed HBV NAT assays, which are particularly sensitive when single samples are tested, are now available and provide an additional, powerful method of determining whether a donor who has been deferred because of anti-HBc reactivity is truly infected by HBV. Due to the availability of FDA-licensed HBV NAT assays and the improved specificity of anti-HBc assays, FDA is recommending in the guidance a reentry algorithm for donors deferred due to falsely positive repeatedly reactive tests for anti-HBc.

In the **Federal Register** of May 21, 2008 (73 FR 29519), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 2008.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified

with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: April 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10046 Filed 4–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0140] (formerly Docket No. FDA–2005D–0261)

Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" dated May 2010. The guidance document provides recommendations to blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for Human Immunodeficiency Virus Type 1 (HIV–1) Nucleic Acid Test (NAT) and Hepatitis C Virus (HCV) NAT, on testing individual samples or pooled samples from donors of human blood and blood components for HIV–1 ribonucleic acid (RNA) and HCV RNA. This guidance also contains recommendations regarding product disposition and donor management based on the results of NAT and serologic testing for markers of HIV–1 and HCV infection on samples, collected at the time of donation, from donors of human blood and blood components. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2005. This guidance also supersedes the recommendations for reentry of donors deferred because of anti-HIV–1 test results, HIV–1 p24 antigen test results, and anti-HCV test results that were provided in the FDA memoranda entitled "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV–1) Transmission by Blood and Blood Products," April 23, 1992; "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; "Recommendations for Donor Screening with a Licensed Test for HIV–1 Antigen," August 8, 1995.

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments on the guidance. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Levine, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry," dated May 2010. The guidance document provides recommendations to blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for Human Immunodeficiency Virus Type 1 (HIV–1) Nucleic Acid Test (NAT) and Hepatitis C Virus (HCV) NAT, on testing individual samples or pooled samples from donors of human blood and blood components for HIV–1 ribonucleic acid (RNA) and HCV RNA. This guidance also contains recommendations regarding product disposition and donor management based on the results of NAT and serologic testing for markers of HIV–1 and HCV infection on samples, collected at the time of donation, from donors of human blood and blood components. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 19, 2005. This guidance also supersedes the recommendations for reentry of donors deferred because of anti-HIV–1 test results, HIV–1 p24 antigen test results, and anti-HCV test results that were provided in the FDA memoranda entitled, "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV–1) Transmission by Blood and Blood Products," April 23, 1992; "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; "Recommendations for Donor Screening with a Licensed Test for HIV–1 Antigen," August 8, 1995.

In the **Federal Register** of July 27, 2005 (70 FR 43439), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except