4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1211]

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry." The draft guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with revised donor deferral recommendations for individuals at increased risk for transmitting human immunodeficiency virus (HIV) infection. The draft guidance document recommends corresponding revisions to donor education materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures. The document also incorporates certain other recommendations related to donor education materials and testing contained in the memorandum to blood establishments entitled, "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products," dated

April 23, 1992 (1992 blood memo). The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry." The emergence of Acquired Immune Deficiency Syndrome (AIDS) in the early 1980s and the recognition that it could be transmitted by blood and blood products had profound effects on the U.S. blood system. Although initially identified in men who have sex with men (MSM) and associated with male-to-male sexual contact, AIDS was soon noted to be potentially transmitted by transfusion of blood components, and by infusion of clotting factor concentrates in individuals with hemophilia. Beginning in 1983, the FDA, issued recommendations for providing donors with education material on risk factors for AIDS and for deferring donors with such risk factors in an effort to prevent transmission of AIDS (later understood to be caused by HIV) by blood and blood products.

Since September 1985, FDA has recommended that blood establishments indefinitely defer male donors who have had sex with another male, even one time, since 1977, due to the strong clustering of AIDS illness in the MSM community and the subsequent discovery of high rates of HIV infection in that population. On April 23, 1992, FDA issued the 1992 blood memo, which contains the current recommendations regarding the deferral for MSM, as well as the deferral recommendations for other persons with behaviors associated with high rates of HIV exposure, namely commercial sex workers, intravenous drug users, and certain other individuals with other risk factors.

The use of donor education material, specific deferral questions and advances in HIV donor testing have reduced the risk of HIV transmission from blood transfusion from about 1 in 2500 units prior to HIV testing to a current estimated residual risk of about 1 in 1.47 million transfusions. During the period from 1997 to 2014, FDA and the Department of Health and

Human Services (HHS) held a number of public meetings, including scientific workshops and meetings of the Blood Products Advisory Committee and the HHS Advisory Committee on Blood Safety and Availability to further review evidence and discuss FDA's blood donor deferral policies to reduce the risk of transmission of HIV by blood and blood products. Studies that might support a policy change were carried out by the Public Health Service agencies in 2011-2014. A policy change to the blood donor deferral period for MSM from indefinite deferral to 1 year since the last sexual contact was announced by the FDA Commissioner in December 2014. The draft guidance, when finalized, will implement that policy change.

In addition to providing donor deferral recommendations for individuals at increased risk for transmitting HIV infection, the draft guidance document incorporates certain recommendations contained in the 1992 blood memo. Certain other recommendations from the 1992 blood memo have not been included in the draft guidance document because they have become outdated over time, superseded by subsequent regulations or guidance documents, or have been incorporated into other guidance documents. However, to ensure that the final guidance document provides comprehensive recommendations for reducing the risk of HIV transmission by blood and blood products, we invite comments on the recommendations contained in the 1992 blood memo that have not been included in the draft guidance. Further, the draft guidance does not provide a specific list of recommended signs and symptoms associated with HIV for inclusion in the donor education materials. We invite comments and the submission of data on what specific signs and symptoms associated with HIV infection would be most appropriate for inclusion in education material in the blood donor setting. The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft 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; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458; and the collections of information in 21 CFR 610.46, 630.6, 640.3 and 640.63 have been approved under OMB control number 0910-0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

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

Dated: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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