4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2175]

Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry; Availability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 "Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry." The draft guidance document provides blood establishments that collect blood and blood components for transfusion or further manufacture, including Source Plasma, with FDA recommendations for assessing blood donor suitability, donor deferral, and blood product management in the event that an outbreak of Ebola virus disease (EVD) with widespread transmission is declared in at least one country. The draft guidance document applies primarily to Ebola virus (species Zaire ebolavirus), but recommendations are expected to apply to other viruses of the Ebolavirus genus such as Sudan virus, Bundibugyo virus, and Taï Forest virus. The recommendations would apply to routine collection of blood and blood components for transfusion or further manufacture, including Source Plasma.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA 2014-D-2175 for "Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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 "Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry." The draft guidance document provides blood establishments that collect blood and blood components for transfusion or further manufacture, including Source Plasma, with FDA recommendations for assessing blood donor suitability, donor deferral, and blood product management in the event that an outbreak of EVD with widespread transmission is declared in at least one country.

Ebola virus is a member of the family Filoviridae that can cause severe hemorrhagic fever in humans and non-human primates with historically high morbidity and mortality rates of

up to 90 percent. However, in the 2014 outbreak in West Africa, the mortality rate has been markedly lower. In humans, EVD is typically characterized at onset by fever, severe headache, muscle pain and weakness, followed by diarrhea, vomiting, abdominal pain, and sometimes diffuse hemorrhage (bleeding or bruising). In previous outbreaks of EVD, symptoms generally appeared within 21 days and most often within 4-10 days following infection; however, based on mathematical models, symptom onset later than 21 days is estimated as possible in 0.1 to 12 percent of cases. In addition, there have been isolated reports of apparently asymptomatic Ebola virus infection in individuals who had contact with Ebola patients.

Transmission of Ebola virus from human to human occurs by direct contact with body fluids (such as blood, urine, stool, saliva, semen, vaginal fluids, or vomit) of symptomatic infected individuals. Therefore, blood and blood products from symptomatic individuals, if they were to donate, would have the potential of transmitting Ebola virus to recipients.

Current regulations 21 CFR 640.3(b) and 21 CFR 640.63(b)(3) require that a donor be in good health with a normal temperature at the time of donation. Standard procedures that are in place to assure that the donor feels healthy at the time of donation serve as an effective safeguard against collecting blood or blood components from a donor who seeks to donate after the onset of clinical symptoms. FDA is providing guidance to reduce the risks of collecting blood and blood components from potentially Ebola virus-infected persons during the asymptomatic incubation period before the onset of clinical symptoms, as well as from individuals with a history of Ebola virus infection or disease.

The draft guidance permits blood establishments to update their donor educational materials to instruct donors with a history of Ebola virus infection or disease to not donate blood or blood components. In the event that one or more countries is designated as having widespread

transmission of Ebola virus, the draft guidance includes recommendations to blood establishments to update their donor history questionnaire (DHQ), including the full-length and abbreviated DHQ and accompanying materials, to assess prospective donors for risk of Ebola virus infection or disease. The draft guidance also includes recommendations to blood establishments to defer indefinitely a blood donor with a history of Ebola virus infection or disease, until more data regarding the persistence of Ebola virus in survivors becomes available. For a donor who in the past 8 weeks has been a resident of or has travelled to a country with widespread transmission of Ebola virus disease, FDA recommends that establishments defer the donor for 8 weeks from the time of the donor's departure from that country. For a donor who has had close contact with a person confirmed or under investigation for Ebola virus infection or disease in whom diagnosis is pending, FDA recommends that establishments defer a donor for 8 weeks after the last close contact that could have resulted in direct contact with body fluids, or 8 weeks after the last sexual contact with a person known to have recovered from Ebola virus disease. In addition, FDA recommends that establishments defer for a period of 8 weeks after exposure a donor who has been notified by a Federal, State, or local public health authority that he or she may have been exposed to a person with Ebola virus disease.

The draft guidance includes FDA recommendations on retrieval and quarantine of blood and blood components from a donor later determined to have Ebola virus infection or disease or risk factors for Ebola virus infection or disease, for notification of consignees, and for reporting a biological product deviation to FDA. The draft guidance also addresses convalescent plasma intended for transfusion.

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 "Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry." 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 606.160(b)(1)(i), 640.3(a) and 640.63(b)(3) have been approved under OMB control number 0910-0116; the collection of information in 21 CFR 606.171 has been approved under OMB control number 0910-0458.

III. 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: November 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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