4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2071]

Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use--Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is announcing the availability of a document titled "Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use--Compliance Policy; Guidance for Industry." This guidance addresses the regulatory requirements for determining donor eligibility that apply to establishments that collect blood and blood components (blood establishments) intended solely for autologous use. On May 22, 2015, in order to better assure the safety of the nation's blood supply and to help protect donor health, FDA finalized its revision of the applicable requirements for blood establishments to test donors for infectious disease, and to determine that donors are eligible to donate and that donations are suitable for transfusion or further manufacture ("Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use" (donor eligibility rule)). The donor eligibility rule includes requirements related to current good manufacturing practice, donation testing, donor eligibility, and donation suitability. It became effective on May 23, 2016.

FDA has developed this guidance in response to questions from blood establishments concerning the applicability of the donor eligibility rule to autologous donations. The guidance

explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

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-2016-D-2071 for "Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use--Compliance Policy; 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.

Submit written requests for single copies of the 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 guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, 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 document entitled "Requirements for Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use--Compliance Policy; Guidance for Industry." We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

This guidance addresses the regulatory requirements for determining donor eligibility that apply to blood establishments that collect blood and blood components intended solely for autologous use described in the final rule entitled, "Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use," 80 FR 29842 (donor eligibility rule)) that became effective on May 23, 2016.

A small proportion of collections of blood and blood components are intended for autologous transfusion. In those instances, the autologous donor presents with a physician's prescription for the collection of the donor's blood for the donor's own upcoming medical (e.g., surgical) procedure. If the donor ultimately does not need the blood, blood establishments may, in some instances, use these donations for allogeneic (i.e. intended for transfusion to a recipient other than the donor) transfusions. This is referred to as "cross-over."

Blood establishments have requested clarification on certain requirements of the donor eligibility rule and the applicability of certain sections of the donor eligibility rule to the collection of blood and blood components intended for autologous use. To address these questions, FDA has developed this guidance to clarify the Agency's policy with respect to the requirements for autologous donors of blood and blood components intended solely for autologous use, (i.e., not subject to cross-over). Specifically, the guidance describes FDA's policy with respect to the following: The requirements in 21 CFR 630.10 related to screening autologous donors for relevant transfusion-transmitted infections; the requirement in 21 CFR 630.15(a)(1)(ii) that the responsible physician examine the autologous donor to permit more frequent collections; and, the requirement in 21 CFR 630.20(a) that the responsible physician determine and document that the autologous donor's health permits the collection of blood and blood components intended for autologous use.

Autologous donors have long been permitted to donate blood for their own use even if they do not meet certain donor eligibility criteria that apply to allogeneic donors because autologous donors are not exposed to new transfusion-transmitted infections in receiving their own blood. For example, FDA does not require testing of autologous donations for Relevant Transfusion-Transmitted Infection (RTTI) unless the donations are used for allogeneic transfusion or shipped to another establishment (21 CFR 610.40(d)). Consistent with this approach to testing autologous donations, FDA does not believe it is necessary to assess autologous donors for risks for RTTI as required in certain provisions in § 630.10 if the donation is intended solely for autologous use.

Sections 630.15(a) and 630.20(a) describe conditions for which a responsible physician must examine and determine and document that the autologous donor's health permits a

collection procedure. Autologous donors are under the care of the physician who prescribes the autologous donation. In light of the medical oversight provided by the autologous donor's physician, FDA believes blood establishments can appropriately protect autologous donors' health by following standard operating procedures that are approved by the responsible physician of the blood establishment and that define criteria for when the autologous donation may proceed and the conditions under which the responsible physician must be consulted.

The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with the donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

The guidance represents the current thinking of the FDA on this topic. 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

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 part 630 have been approved under OMB control number 0910-0795.

III. Electronic Access

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

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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