DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 630 and 640

[Docket No. FDA–2022–D–0588]

Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements.'' The guidance document addresses certain requirements that apply to blood establishments that collect blood and blood components, including Source Plasma. Specifically, 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 requirements in FDA's regulations regarding donation suitability, donor eligibility, and quarantine hold for Source Plasma. FDA expects that the compliance policy described in the guidance will increase the availability of blood and blood components, including Source Plasma, while maintaining the health of blood donors and the safety of blood and blood components. The guidance announced in this document finalizes the draft guidance of the same title dated May 2022, and supersedes the guidance entitled ''Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency; Guidance for Industry,'' dated April 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on October 18, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2022–D–0588 for ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: Phillip Kurs, 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 ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma

Quarantine Hold Requirements.'' The guidance document addresses certain requirements that apply to blood establishments that collect blood and blood components, including Source Plasma. Specifically, 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 requirements in Title 21 of the Code of Federal Regulations (21 CFR 630.30) regarding donation suitability; 21 CFR 630.10(c)(2) regarding donor eligibility; and 21 CFR 640.69(f) regarding quarantine hold for Source Plasma.

In the **Federal Register** of May 24, 2022 (87 FR 31440), FDA announced the availability of the draft guidance of the same title dated May 2022. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes clarifying the format of the report discussed in the guidance and clarifying the scope of the compliance policy. In addition, editorial changes were made to improve clarity. The guidance announced in this document finalizes the draft guidance dated May 2022, and supersedes the guidance entitled ''Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency; Guidance for Industry,'' dated April 2020.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements.'' 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 contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved under OMB control number 0910–0116. This guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338 and the collections of information in 21 CFR parts 606, 630, and 640 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice 12153]

RIN 1400–AE00

Public Access to Information

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (the Department) finalizes the proposed rule it published on March 3, 2020, relating to the availability to the public of information that is under the control of the Department. These changes were prompted by changes in the law governing disclosure of such information, including the Freedom of Information Act Improvement Act of 2016. This final rule reflects changes in the FOIA and consequent changes in the Department's procedures since the last major revision of the Department's regulations on public access to information, which occurred in 2016.

DATES: This rule is effective on November 17, 2023.

FOR FURTHER INFORMATION CONTACT: Kellie Robinson, Office of Information Programs and Services, *FOIAstatus@state.gov,* 202–261–8484.

SUPPLEMENTARY INFORMATION: This rule finalizes the Notice of Proposed Rulemaking that was published on March 3, 2020. 85 FR 13104. It implements the Freedom of Information Act (FOIA) Improvement Act of 2016, Public Law 114–185, and updates the Department's FOIA regulations at 22 CFR part 171. The following summary of the substantive changes to Part 171 was included in the NPRM but is provided here for convenience.

The rule, in § 171.4, provides updated procedures and addresses for submitting FOIA requests to the Department, including procedures for requesting information about the requester and requests for visa information.

Subpart B of the rule (§§ 171.10 through 171.17) contains the rules governing the processing of a FOIA request. Section 171.11 covers the Department's initial processing of a request; it clarifies the information that is to be provided as part of a request, the Department's process for responding to requests, and consultation and referral with respect to requests. Section 171.12 covers the timing of responses to a request, including multi-track processing, expedited processing, and ''unusual circumstances'' (as defined in the FOIA) that might affect the Department's ability to respond. Section 171.13 covers responses to requests, including the procedures upon denial of a request. The updates add a provision for consultation with the Department of Justice's Office of Information Policy with respect to invocation of a FOIA exclusion. Section 171.14 modifies the Department's process with respect to reviews of confidential commercial information, including procedures for the owner of the information to object to the release of the information.

Section 171.15 revises the timeline for submission of appeals to 90 days and provides for information to be given to requesters about dispute resolution services at various stages of the processing of a request, in accordance with the FOIA Improvement Act of 2016. Section 171.16 provides updates on the fees to be charged for FOIA requests, including how fees are calculated. This section provides an updated explanation of the term, ''representative of the news media.''

Subpart C contains the rule's Privacy Act provisions. There are two substantive changes in this subpart from that published in the NPRM. The first relates to a Privacy Act exemption that was published after the NPRM was published. *See* the final rule on March 9, 2020, ''Privacy Act; STATE–01, Email Archive Management Records,'' 85 FR 13482. This SORN was added to the lists in paragraph (a)(2)(iii), and (b)(1), (2), (3), (4), (5), (6) and (7). However, the Department has now determined that this item was added in error, and the Department is removing STATE–01 from the lists of Privacy Act exemptions in §§ 171.26(a)(2)(iii), (b)(2), (b)(3), (b)(4), (b)(5), (b)(6), and (b)(7). The reason for this action is that the Department has determined that its email records do not constitute a system of records under the Privacy Act; therefore, STATE–01, ''Email Archive Management Records'', will be