**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Dispute Resolution Procedures for Science-Based Decisions on Products by the Center for Veterinary Medicine—21 CFR 10.75**

*OMB Control Number 0910–0566—Extension*

The Center for Veterinary Medicine (CVM) Guidance for Industry (GFI) #79, ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' (*https://www.fda.gov/media/70279/download),* describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. The guidance details information on how CVM intends to apply provisions of existing regulations regarding internal review of Agency decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers of animal drugs or other products regulated by CVM who wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established procedures discussed in the guidance.

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedures found in GFI #79.

In the **Federal Register** of August 18, 2020 (85 FR 50827), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR part; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 10.75, Request for review of a scientific dispute ..... | 1 | 4 | 4 | 10 | 40 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We note that the 60-day notice included an inadvertent error in the estimated burden, which has been corrected in table 1. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 11, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–03431 Filed 2–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–6931]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and ''Lookback''

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information requirements relating to FDA's regulation of current good manufacturing practice (CGMP) and related regulations for blood and blood components; and requirements for donation testing, donor notification, and ''lookback''.

**DATES:** Submit either electronic or written comments on the collection of information by April 23, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 23, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**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–2017–N–6931 for ''Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and 'Lookback'.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and ''Lookback''**

*OMB Control Number 0910–0116—Extension*

This information collection supports Agency regulations. All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacturing into products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic Act (FD&C Act) also applies to biological products. Blood and blood components for transfusion or for further manufacturing into products are drugs, as that term is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the FD&C Act, blood and plasma establishments must comply with the provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351(a)), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform to CGMP and related regulations.

The CGMP regulations (part 606) (21 CFR part 606) and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donations for evidence of relevant transfusion-transmitted infections and in notifying donors is to prevent the transmission of relevant transfusion-transmitted infections. For example, the ''lookback'' requirements are intended

to help ensure the continued safety of the blood supply by providing necessary information to consignees of blood and blood components and appropriate notification of recipients of blood components that are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donation testing, donor notification, and ''lookback'' regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections.

The recordkeeping requirements serve preventive and remedial purposes. The third-party disclosure requirements identify various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA's Center for Biologics Evaluation and Research (CBER) of certain information that may require immediate corrective action.

Respondents to this collection of information are licensed and unlicensed blood establishments that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 864 licensed Source Plasma establishments and approximately 1,789 licensed blood collection establishments, for an estimated total of 2,653 (864 + 1,789) licensed blood collection establishments. Also, there are an estimated total of 817 unlicensed, registered blood collection establishments for an approximate total of 3,470 collection establishments (864 + 1,789 + 817 = 3,470 establishments). Of these establishments, approximately 856 perform plateletpheresis (777) and leukapheresis (79). These establishments annually collect approximately 73.7 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA ''lookback'' procedures. In addition, there are another estimated 4,961 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The following reporting and recordkeeping estimates are based on information provided by industry, CMS, and FDA experience. Based on information from industry, we estimate that there are approximately 53.5 million donations of Source Plasma from approximately 2.5 million donors and approximately 12.3 million donations of Whole Blood and apheresis Red Blood Cells including approximately 10,000 (approximately 0.081 percent of 12.3 million) autologous donations, from approximately 9 million donors. Assuming each autologous donor makes an average of 1.1 donations, FDA estimates that there are approximately 9,090 autologous donors (10,000 autologous/1.1 average donations).

FDA estimates that approximately 0.53 percent (56,000 ÷ 10,654,000) of the 77,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors' testing provisions in § 610.40(c)(1)(ii).

Under §§ 610.40(g)(2) and (h)(2)(ii)(A), Source Leukocytes, a licensed product that is used in the manufacture of interferon, which requires rapid preparation from blood, is currently shipped prior to completion of testing for evidence of relevant transfusion-transmitted infections. Shipments of Source Leukocytes are approved under a biologics license application and each shipment does not have to be reported to the Agency. Based on information from CBER's database system, FDA receives less than one application per year from manufacturers of Source Leukocytes. However, for calculation purposes, we are estimating one application annually.

According to CBER's database system, there are approximately 15 licensed manufacturers that ship known reactive human blood or blood components under §§ 610.40(h)(2)(ii)(C) and (D). FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood components per month (12 per year) that would require two labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D).

Based on information received from industry, we estimate that approximately 7,500 donations that test reactive by a screening test for syphilis and are determined to be biological false positives by additional testing annually. These units would be labeled according to § 610.40(h)(2)(vi).

Human blood or a blood component with a reactive screening test, as a component of a medical device, is an integral part of the medical device, *e.g.* a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement indicating that the product was manufactured from a donation found to be reactive for the identified relevant transfusion-transmitted infection(s). In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, then a warning statement must be affixed to the medical device. To account for this rare occasion under § 610.42(a), we estimate that the warning statement would be necessary no more than once a year.

FDA estimates that approximately 3,100 repeat donors will test reactive on a screening test for HIV. We also estimate that an average of three components was made from each donation. Under §§ 610.46(a)(1)(ii)(B) and (a)(3), this estimate results in 9,300 (3,100 × 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 9,300 (3,100 × 3) notifications to consignees of subsequent test results.

We estimate that approximately 4,961 consignees will be required under § 610.46(b)(3) to notify transfusion recipients, their legal representatives, or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors × 3) notifications. Also, under § 610.46(b)(3), we estimate and include the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, we estimate that approximately 6,800 repeat donors per year would test reactive for antibody to HCV. Under §§ 610.47(a)(1)(ii)(B) and 610.47(a)(3), collecting establishments would notify the consignee 2 times for each of the 20,400 (6,800 × 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 40,800 (2 × 20,400) notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,961 consignees would notify approximately

2,050 recipients or their physicians of record annually.

Based on industry estimates, approximately 18.15 percent of approximately 14,018,000 million potential donors (2,544,000 donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 2,606 (1,789 + 817) blood collecting establishments to notify onsite and to explain why the donor is determined not to be suitable for donating. Based on such available information, we estimate that two-thirds (1,737) of the 2,606 blood collecting establishments provided onsite additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, we estimate that only approximately one-third, or 869 of the 2,606 blood collecting establishments would need to provide, under § 630.40(a), additional information and onsite counseling to the estimated 848,000 (one-third of approximately 2,544,000) ineligible donors.

It is estimated that another 0.6 percent of 14,018,000 potential donors (84,108 donors) are deferred annually based on test results. We estimate that approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who have reactive test results for HIV, Hepatitis B Virus, HCV, Human T-Lymphotropic Virus, and syphilis as usual and customary business practice. Consequently, 5 percent of the 2,653 licensed establishments (133) collecting 1 percent (841) of the deferred donors (84,108) would notify donors under § 630.40(a).

As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.40(d)(1). However, we estimate that approximately 5 percent of the 1,789 blood collection establishments (89) may not notify the referring physicians of the estimated 2 percent of 10,000 autologous donors with the initial reactive test results (200) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95 percent of the recordkeepers, which collect 99 percent of the blood supply, have developed standard operating procedures (SOPs) as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(ix), we estimate the total annual records based on the approximately 2,544,000 donors determined not to be eligible to donate and each of the estimated 2,628,108 (2,544,000 + 84,108) donors deferred based on reactive test results for evidence of infection because of relevant transfusion-transmitted infections. Under § 606.160(b)(1)(xi), only the 1,789 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 9,090 autologous donors (409) will be deferred under § 610.41, which in turn will lead to the notification of their referring physicians.

Under § 610.41(b), FDA estimates that there would be 25 submissions for requalification of donors each requiring 7 hours per submission. In addition, FDA estimates that there would be only 3 notifications for requalification of donors under § 630.35(b) which would also require 7 hours for each submission.

FDA permits the shipment of untested or incompletely tested human blood or blood components in rare medical emergencies and when appropriately documented (§ 610.40(g)(1)). We estimate the recordkeeping under § 610.40(g)(1) to be minimal with one or fewer occurrences per year. The reporting of test results to the consignee in § 610.40(g) is part of the usual and customary business practice of blood establishments.

The average burden per response (hours) and average burden per recordkeeping (hours) are based on estimates received from industry or FDA experience with similar reporting or recordkeeping requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 606.170(b)[2]; Donor or recipient fatality reporting | 81 | 1 | 81 | 20 | 1,620 |
| 610.40(g)(2); Application for approval to ship | 1 | 1 | 1 | 1 | 1 |
| 610.41(b); Request for requalification of donor | 2,653 | 0.0094 | 25 | 7 | 175 |
| 610.40(h)(2)(ii)(A); Application for approval for shipment or use | 1 | 1 | 1 | 1 | 1 |
| 630.35(b); Request for requalification of donor | 2,653 | 0.00113 | 3 | 7 | 21 |
| Total | | | | | 1,818 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section; activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 606.100(b); [2] Maintenance of SOPs | [5] 422 | 1 | 422 | 24 | 10,128 |
| 606.100(c); Records of investigations | [5] 422 | 10 | 4,220 | 1 | 4,220 |
| 606.110(a); [3] Documentation donor's health permits plateletpheresis or leukapheresis. | [6] 43 | 1 | 43 | 0.5 (30 minutes) | 22 |
| 606.151(e); Records of emergency transfusions | [5] 422 | 12 | 5,064 | 0.08 (5 minutes) | 405 |

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

| 21 CFR section; activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 606.160; [4] Records of collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components. | [5] 422 | 907.583 | 383,000 | 0.75 (45 minutes) | 287,250 |
| 606.160(b)(1)(viii); HIV consignee notification | 1,789 | 10.4533 | 18,701 | 0.17 (10 minutes) | 3,179 |
| | 4,961 | 3.6537 | 18,126 | 0.17 (10 minutes) | 3,081 |
| 606.160(b)(1)(viii); HCV consignee notification | 1,789 | 22.8060 | 40,800 | 0.17 (10 minutes) | 6,936 |
| | 4,961 | 8.2241 | 40,800 | 0.17 (10 minutes) | 6,936 |
| HIV recipient notification | 4,961 | 0.3538 | 1,755 | 0.17 (10 minutes) | 298 |
| HCV recipient notification | 4,961 | 0.4132 | 2,050 | 0.17 (10 minutes) | 349 |
| 606.160(b)(1)(ix); Donor notification records | 3,470 | 757.380 | 2,628,109 | 0.05 (3 minutes) | 131,405 |
| 606.160(b)(1)(xi); Physician notification records | 1,789 | 0.2286 | 409 | 0.05 (3 minutes) | 20.5 |
| 606.165; Distribution and receipt records | [5] 422 | 907.583 | 383,000 | 0.08 (5 minutes) | 30,640 |
| 606.170(a); Adverse reaction records | [5] 422 | 12 | 5,064 | 1 | 5,064 |
| 610.40(g)(1); Documentation of medical emergency | 3,470 | 1 | 3,470 | 0.5 (30 minutes) | 1,735 |
| 630.15(a)(1)(ii)(B); Documentation required for dedicated donation. | 1,789 | 1 | 1,789 | 1 | 1,789 |
| 630.20(c); Documentation of exceptional medical need | 1,789 | 1 | 1,789 | 1 | 1,789 |
| Total | | | | | 495,247 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 606.171, 630.5(d), 630.10(c)(1) and (2), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3] The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4] The recordkeeping requirements in §§ 606.110(a)(2), 630.5(b)(1)(i), 630.10(f)(2) and (4), 630.10(g)(2)(i), 630.15(a)(1)(ii)(A) and (B), 630.15(b)(2), (b)(7)(i) and (iii), 630.20(a) and (b), 640.21(e)(4), 640.25(b)(4) and (c)(1), 640.31(b), 640.33(b), 640.51(b), 640.53(b) and (c), 640.56(b) and (d), 630.15(b)(2), 640.65(b)(2)(i), 640.65(b)(2)(i), 640.71(b)(1), 640.72, 640.73, and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments ($0.05 \times 4,961 + 3,470 = 422$).
[6] Five percent of plateletpheresis and leukapheresis establishments ($0.05 \times 856 = 43$).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| 606.145(c); Notification of bacterial contamination of platelets. | 4,961 | 0.2822 | 1,400 | 0.02 (90 seconds). | 28 |
| 606.170(a); Reports of transfusion reaction | [2] 422 | 12 | 5,064 | 0.5 (30 minutes) | 2,532 |
| 610.40(c)(1)(ii); Labeling of donation dedicated to single recipient. | 3,470 | 0.0395 | 137 | 0.08 (5 minutes) | 11 |
| 610.40(h)(2)(ii)(C) and (D); Labeling of reactive blood and blood components. | 15 | 12 | 180 | 0.2 (12 minutes) | 36 |
| 610.40(h)(2)(vi); Labeling of reactive blood and blood components. | 3,470 | 2.1614 | 7,500 | 0.08 (5 minutes) | 600 |
| 610.42(a); Warning statement for medical devices | 1 | 1 | 1 | 1 | 1 |
| 610.46(a)(1)(ii)(B); Notification to consignees to quarantine (HIV ''lookback''). | 1,789 | 5.1984 | 9,300 | 0.17 (10 minutes) | 1,581 |
| 610.46(a)(3); Notification to consignees of further testing. | 1,789 | 5.1984 | 9,300 | 0.17 (10 minutes) | 1,581 |
| 610.46(b)(3); Notification to recipients | 4,961 | 0.3528 | 1,750 | 1 | 1,750 |
| 610.47(a)(1)(ii)(B); Notification to consignees to quarantine (HCV ''lookback''). | 1,789 | 11.4030 | 20,400 | 0.17 (10 minutes) | 3,468 |
| 610.47(a)(3); Notification to consignees of further testing. | 1,789 | 11.4030 | 20,400 | 0.17 (10 minutes) | 3,468 |
| 610.47(b)(3); Notification to recipients | 4,961 | 0.4132 | 2,050 | 1 | 2,050 |
| 630.40(a); Notification of donors determined not to be eligible for donation. | 869 | 975.834 | 848,000 | 0.08 (5 minutes) | 67,840 |
| 630.40(a); Notification of donors deferred based on reactive test results. | 133 | 6.323 | 841 | 1.5 | 1,262 |
| 630.40(d)(1); Notification to physician of autologous donor. | 89 | 2.247 | 200 | 1 | 200 |
| Total | | | | | 86,408 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments ($0.05 \times 4,961 + 3,470 = 422$).

The burden for this information collection has changed since the last OMB approval. FDA estimates that the total burden for this collection will be 583,473 hours (1,818 reporting + 495,247 recordkeeping + 86,408 third-party disclosure). Our estimated burden for the information collection reflects an overall increase of 79,024 hours. We attribute this adjustment to an increase in the number of blood establishments during the last 3 years.

Dated: February 10, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–03434 Filed 2–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Presidential Advisory Council on HIV/AIDS

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services .

**ACTION:** Notice of a virtual meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 70th full Council meeting utilizing virtual technology on March 8–March 9, 2021.

**DATES:** The meeting will be held on Monday, March 8 and Tuesday, March 9, 2021, from approximately 2:00 p.m. to 5:00 p.m. (ET) on both days. This meeting will be conducted utilizing virtual technology.

**ADDRESSES:** Instructions on attending this meeting virtually will be posted one week prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

**FOR FURTHER INFORMATION CONTACT:** Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

**SUPPLEMENTARY INFORMATION:** PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. The meeting will be open to the public; a public comment session will be held during the meeting and PACHA members would like to hear from you, specifically:

(1) What are the most meaningful actions that can be taken to implement the HIV National Strategic Plan and improve implementation of the Ending the HIV Epidemic initiative at the national level and in your community to meet the goal of ending HIV; and

(2) How can domestic HIV/AIDS programs better meet the needs of underserved communities and address the systemic barriers that communities face in order to achieve the goals of the President's Executive Order Advancing Racial Equity and Support for Underserved Communities? The Executive Order can be found here: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

Pre-registration is required to provide public comment during the meeting. To pre-register to attend or to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, March 1, 2021. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Tuesday, March 16, 2021. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

Dated: February 11, 2021.

**B. Kaye Hayes,**

*Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.*

[FR Doc. 2021–03524 Filed 2–19–21; 8:45 am]

**BILLING CODE 4150–43–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0330]**

### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before April 23, 2021.

**ADDRESSES:** Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990–0330–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Appellant Climate Survey.

*Type of Collection:* Revision.

OMB No. 0990–0330.

*Abstract:* The annual OMHA Appellant Climate Survey is a survey of Medicare beneficiaries, providers, suppliers, or their representatives who participated in a hearing before an Administrative Law Judge (ALJ) from OMHA. Appellants dissatisfied with the