''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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; or Stephen Ripley, 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: In the **Federal Register** of December 15, 2017, FDA published a notice of availability with a 60-day comment period to request comments on draft guidance for industry and FDA staff entitled ''The Least Burdensome Provisions: Concept and Principles.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act. 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. This draft guidance is not subject to Executive Order 12866.

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until March 15, 2018. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

Dated: January 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01122 Filed 1–22–18; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 March 26, 2018.

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 March 26, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 26, 2018. 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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

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 of certain information that may require immediate corrective action.

Under the reporting requirements, § 606.170(b), in brief, requires that facilities notify FDA's Center for Biologics Evaluation and Research

(CBER), as soon as possible after a complication of blood collection or transfusion is confirmed to be fatal. The collecting facility is required to report donor fatalities, and the compatibility testing facility is to report recipient fatalities. The regulation also requires the reporting facility to submit a written report of the investigation within 7 days after the fatality. In Fiscal Year 2016, FDA received 81 fatality reports.

Section 610.40(g)(2) (21 CFR 610.40(g)(2)) requires an establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use prior to completion of testing for evidence of infection due to relevant transfusion-transmitted infections.

Section 610.41(b) allows for a previously deferred donor to subsequently be found to be an eligible donor of blood and blood components by a requalification method or process found acceptable for such purposes by FDA.

Section 610.40(h)(2)(ii)(A), in brief, requires an establishment to obtain written approval from FDA to use or ship human blood or blood components found to be reactive by a screening test for evidence of infection due to a relevant transfusion-transmitted infection(s) or collected from a donor deferred under § 610.41(a).

In addition, § 630.35(b) (21 CFR 630.35(b)) allows for a previously deferred donor, deferred for reasons other than § 610.41(b) to become requalified for donation by a method or process found acceptable for such purpose by FDA.

Under the third-party disclosure requirements, § 606.145(c) requires transfusion services to notify certain blood collection establishments concerning bacterial contamination of platelets. In table 3, FDA estimates that for the approximately 4,961 transfusion services, there would be 1,400 total notifications per year to blood collection establishments (700 notifications that platelets are bacterially contaminated and 700 notifications per year concerning the identity or non-identity of the species of the contaminating organism).

Section 610.40(c)(1)(ii) in part 610, in brief, requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121 and with a label containing the name and identifying information of the recipient. The information collection requirements under § 606.121 are part of usual and customary business practice.

Sections 610.40(h)(2)(ii)(C) and (D), in brief, require an establishment to label certain reactive human blood and blood components with the appropriate screening test results for evidence of infection due to the identified relevant transfusion-transmitted infection(s), and, if they are intended for further manufacturing use into products, to include a statement on the label indicating the exempted use specifically approved by FDA. Also, § 610.40(h)(2)(vi) requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results.

Section 610.42(a) requires a warning statement ''indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified relevant transfusion-transmitted infection(s)'' in the labeling for medical devices containing human blood or a blood component found to be reactive by a screening test for evidence of infection due to a relevant transfusion-transmitted infection(s) or syphilis.

In addition, § 630.35(b) allows for a previously deferred donor, deferred for reasons other than § 610.41(b) to become requalified for donation by a method or process found acceptable for such purpose by FDA.

In brief, §§ 610.46 and 610.47 require blood collecting establishments to establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when: (1) A donor tests reactive for evidence of HIV or HCV infection or (2) the collecting establishment becomes aware of other reliable test results or information indicating evidence of HIV or HCV infection (see §§ 610.46(a)(1) and 610.47(a)(1)). The requirement for ''an appropriate system'' requires the collecting establishment to design standard operating procedures (SOPs) to identify and quarantine all blood and blood components previously collected from a donor who later tests reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection. Within 3 calendar days of the donor testing reactive by an HIV or HCV screening test or the collecting establishment becoming aware of other reliable test results or information, the collecting establishment must, among other things, notify consignees to quarantine all identified previously collected in-date blood and blood components (§§ 610.46(a)(1)(ii)(B) and 610.47(a)(1)(ii)(B)) and, within 45 days, notify the consignees of supplemental test results, or the results of a reactive screening test if there is no available supplemental test that is approved for such use by FDA (§§ 610.46(a)(3) and 610.47(a)(3)).

Consignees also must establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when notified by the collecting establishment that they have received blood and blood components previously collected from donors who later tested reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection in a donor (§§ 610.46(b) and 610.47(b)). This provision for a system requires the consignee to establish SOPs for, among other things, notifying transfusion recipients of blood and blood components, or the recipient's physician of record or legal representative, when such action is indicated by the results of the supplemental (additional, more specific) tests or a reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or an investigational device exemption (IDE), is exempted for such use by FDA. The consignee must make reasonable attempts to perform the notification within 12 weeks of receipt of the supplemental test result or receipt of a reactive screening test result when there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA (§§ 610.46(b)(3) and 610.47(b)(3)).

Section 630.40(a) requires an establishment to make reasonable attempts to notify any donor who has been deferred as required by § 610.41(a), or who has been determined not to be eligible as a donor. Section 630.40(d)(1) requires an establishment to provide certain information to the referring physician of an autologous donor who is deferred based on the results of tests as described in § 610.41.

Under the recordkeeping requirements, § 606.100(b), in brief, requires that written SOPs be maintained for all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components used for transfusion and further manufacturing purposes. Section 606.100(c) requires the review of all records pertinent to the lot or unit of blood prior to release or distribution. Any unexplained discrepancy or the failure of a lot or unit of final product

to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded.

In brief, § 606.110(a) provides that the use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for that specific product if, among other things, the physician determines and documents that the donor's health permits plateletpheresis or leukapheresis. Section 606.110(b) requires establishments to request prior approval from CBER for plasmapheresis of donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are approved under OMB control number 0910–0338 and, therefore, are not reflected in the tables of this document.

Section 606.151(e) requires that SOPs for compatibility testing include procedures to expedite transfusion in life-threatening emergencies; records of all such incidents must be maintained, including complete documentation justifying the emergency action, which must be signed by a physician.

Section 606.171 requires establishments to establish and maintain procedures related to product deviations. The burden for the recordkeeping requirements under § 606.171 are included under § 606.100.

So that each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components can be clearly traced, § 606.160 requires that legible and indelible contemporaneous records of each such step be made and maintained for no less than 10 years. Section 606.160(b)(1)(viii) requires records of the quarantine, notification, testing and disposition performed under the HIV and HCV ''lookback'' provisions. Furthermore, § 606.160(b)(1)(x) requires a blood collection establishment to maintain records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup. Section 606.160(b)(1)(xi) requires an establishment to maintain records of notification of the referring physician of a deferred autologous donor, including appropriate followup.

Section 606.165, in brief, requires that distribution and receipt records be maintained to facilitate recalls, if necessary.

Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions arising as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. Section 606.170(a) also requires that when an investigation determines that the product caused the transfusion reaction, copies of all such written reports must be forwarded to and maintained by the manufacturer or collecting facility.

Section 610.40(g)(1) requires an establishment to appropriately document a medical emergency for the release of human blood or blood components prior to completion of required testing.

Under § 630.15(a)(1)(ii)(B), FDA requires that for a dedicated donation based on the intended recipient's documented exceptional medical need, the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

Under § 630.20(c), a collection establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a), if the donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

In addition to the CGMP regulations in part 606, there are regulations in part 630 that include requirements for blood and blood components intended for transfusion or further manufacturing use, and part 640 that require additional standards for certain blood and blood products as follows: Sections 630.5(b)(1)(i), 630.5(d), 630.10(c)(1) and (2), 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); 640.25(b)(4) and (c)(1); 640.21(e)(4); 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); 640.66; 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in tables 1 and 2.

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 569 licensed Source Plasma establishments and approximately 1,054 licensed blood collection establishments, for an estimated total of 1,623 (569 + 1,054) licensed blood collection establishments. Also, there are an estimated total of 680 unlicensed, registered blood collection establishments for an approximate total of 2,303 collection establishments (569 + 1,054 + 680 = 2,303 establishments). Of these establishments, approximately 901 perform plateletpheresis and leukopheresis. These establishments annually collect approximately 53.3 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 38.3 million donations of Source Plasma from approximately 2 million donors and approximately 15 million donations of Whole Blood and apheresis Red Blood Cells including approximately 34,500 (approximately 0.23 percent of 15 million) autologous donations, from approximately 10.9 million donors. Assuming each autologous donor makes an average of 1.1 donations, FDA estimates that there are approximately 31,364 autologous donors (34,500 autologous/1.1 average donations).

FDA estimates that approximately 0.19 percent (21,000/10,794,000) of the 72,000 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 7,544 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 3,021 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 9,063 (3,012 × 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 9,063 (3,021 × 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 6,799 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 20,397 (6,799 × 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 40,794 (2 × 20,397 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 14.3 percent of approximately 9 million potential donors (1,287,000 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 1,734 (1,054 + 680) 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 (1,156) of the 1,734 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 578 of the 1,734 blood collecting establishments would need to provide, under § 630.40(a), additional information and onsite counseling to the estimated 429,000 (one-third of approximately 1,287,000) ineligible donors.

It is estimated that another 4.5 percent of 10 million potential donors (450,000 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 1,623 licensed establishments (81) collecting 1 percent (4,050) of the deferred donors (405,000) 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 1,054 blood collection establishments (53) may not notify the referring physicians of the estimated 2 percent of 31,364 autologous donors with the initial reactive test results (627) 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 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 1,287,000 donors determined not to be eligible to donate and each of the estimated 1,692,000 (1,287,000 + 405,000) 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 1,734 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 31,364 autologous donors (1,411) 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.170(b) [2]	81	1	81	20	1,620
610.40(g)(2)	1	1	1	1	1
610.41(b)	1,623	0.015	25	7	175
610.40(h)(2)(ii)(A)	1	1	1	1	1
630.35(b)	1,623	0.002	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]	[5] 363	1	363	24	8,712
606.100(c)	[5] 363	10	3,630	1	3,630
606.110(a) [3]	[6] 45	1	45	.5 (30 min.)	23
606.151(e)	[5] 363	12	4,356	.08 (5 min.)	348
606.160 [4]	[5] 363	1,055.096	383,000	.75 (45 min.)	287,250
606.160(b)(1)(viii) HIV consignee notification	1,734	10.4533	18,126	.17 (10 min.)	3,081
	4,961	3.6537	18,126	.17 (10 min.)	3,081
606.160(b)(1)(viii) HCV consignee notification	1,734	23.5259	40,794	.17 (10 min.)	6,935
	4,961	8.2229	40,794	.17 (10 min.)	6,935
HIV recipient notification	4,961	0.3538	1,755	.17 (10 min.)	298
HCV recipient notification	4,961	0.4132	2,050	.17 (10 min.)	349
606.160(b)(1)(ix)	2,303	734.6939	1,692,000	.05 (3 min.)	84,600
606.160(b)(1)(xi)	1,734	0.8137	1,411	.05 (3 min.)	71
606.165	[5] 363	1,055.096	383,000	.08 (5 min.)	30,640
606.170(a)	[5] 363	12	4,356	1	4,356
610.40(g)(1)	2,303	1	2,303	.5 (30 min.)	1,152
630.15(a)(1)(ii)(B)	1,734	1	1,734	1	1,734
630.20(c)	1,734	1	1,734	1	1,734
Total					444,930

[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), 630.109(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); 640.71(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 ($0.05 \times 4{,}961 + 2{,}303 = 363$).
[6] Five percent of plateletpheresis and leukopheresis establishments ($0.05 \times 901 = 45$).

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.145(c)	4,961	0.2822	1,400	.02	28
606.170(a)	[2] 363	12	4,356	.5 (30 min.)	2,178
610.40(c)(1)(ii)	2,303	0.0595	137	.08 (5 min.)	11
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	15	12	180	.20 (12 min.)	36
610.40(h)(2)(vi)	2,303	3.28	7,554	.08 (5 min.)	604
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,734	5.2266	9,063	.17 (10 min.)	1,541
610.46(a)(3)	1,734	5.2266	9,063	.17 (10 min.)	1,541
610.46(b)(3)	4,961	0.3538	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,734	11.7630	20,397	.17 (10 min.)	3,467

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.47(a)(3)	1,734	11.7630	20,397	.17 (10 min.)	3,467
610.47(b)(3)	4,961	0.4132	2,050	1	2,050
630.40(a) [3]	578	742.214	429,000	.08 (5 min.)	34,320
630.40(a) [4]	81	50.00	4,050	1.5	6,075
630.40(d)(1)	53	11.83	627	1	627
Total					57,701

[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 × 4,961 + 2,303 = 363).
[3] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4] Notification of donors deferred based on reactive test results for evidence of infection due to relevant transfusion-transmitted infections.

The burden for this information collection has changed since the last OMB approval. Because of a slight decrease in the number of blood establishments during the last 3 years, FDA has decreased our recordkeeping and third party disclosure burden estimates.

Dated: January 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01123 Filed 1–22–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) announces the third meeting of the Tick-Borne Disease Working Group (Working Group) on February 12, 2018, from 12:00 p.m. to 4:00 p.m., Eastern Time. For this third meeting, the Working Group will focus on mapping out the work of the six Subcommittee Meeting Working Groups that were established on December 12, 2017. These subcommittees were established to assist the Working Group with the development of the report to Congress and the HHS Secretary as required by the 21st Century Cures Act. The subcommittees are:

1. Disease Vectors, Surveillance and Prevention (includes epidemiology of tick-borne diseases);

2. Pathogenesis, Transmission, and Treatment;

3. Testing and Diagnostics (including laboratory-based diagnoses and clinical-diagnoses);

4. Access to Care Services and Support to Patients;

5. Vaccine and Therapeutics; and

6. Other Tick-Borne Diseases and Co-infections.

DATES: February 12, 2018, from 12:00 p.m. to 4:00 p.m., Eastern Time.

ADDRESSES: This will be a virtual meeting that is held via webcast. Members of the public may attend the meeting via webcast and instructions for attending this virtual meeting will be posted one week prior to the meeting at: *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html.*

FOR FURTHER INFORMATION CONTACT: James Berger, Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services; via email at *tickbornedisease@hhs.gov* or by phone at 202–795–7697.

SUPPLEMENTARY INFORMATION: At this meeting, the Working Group will also hear about one or more examples of other efforts that have been successfully undertaken to define a national or statewide approach to preventing, monitoring, diagnosing, and treating people with tick-borne diseases. In addition, federal resources, within and outside of HHS, that may be of use to the subcommittees as they do their work, such as the Department of Health and Human Services Internal Working Group on Lyme and Other Tick-Borne Diseases, will be presented.

The Working Group invites public comment on issues related to the Working Group's charge. Comments may be provided over the phone during the meeting or in writing. Persons who wish to provide comments by phone should review directions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html* before submitting a request via email at *tickbornedisease@hhs.gov* on or before February 7, 2018. Phone comments will be limited to three minutes each to accommodate as many speakers as possible. A total of 30 minutes will be allocated to public comments. If more requests are received than can be accommodated, speakers will be randomly selected. The nature of the comments will not be considered in making this selection. Public comments may also be provided in writing. Individuals who would like to provide written comment should review directions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html* before sending their comments to *tickbornedisease@hhs.gov* on or before February 7, 2018.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with section 2062 of the *21st Century Cures Act,* and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review all HHS efforts related to tick-borne diseases to help ensure interagency coordination and minimize overlap, examine research priorities, and identify and address unmet needs. In addition, the Working Group will report to the Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease prevention, treatment and research, and addressing gaps in those areas.

Dated: January 17, 2018.

James Berger,

Alternate Designated Federal Officer, Office of HIV/AIDS and Infectious Disease Policy, Tick-Borne Disease Working Group.

[FR Doc. 2018–01149 Filed 1–22–18; 8:45 am]

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