1. Product name.

2. Application number.

3. Chemical name and structure.

4. Proposed indication(s) or context of product development.

5. Background section that includes a brief history of the development program and the events leading up to the meeting, and the status of product development.

6. Proposed agenda, including estimated times needed for discussion of each agenda item.

7. List of questions for discussion with a brief summary for each question to explain the need or context for the question.

8. Drug development issue (*e.g.,* dosing, clinical trial design, safety prediction), including the proposed MIDD approach to the solution, information to support discussion (*e.g.,* a description of the data used for developing the models, model development, simulation plan, results), and how the Agency can help guide any next steps relative to the regulatory decision making process, which should be summarized and clearly articulated with any supporting data imperative to the discussion.

E. Meeting Summaries

A meeting summary will be sent to the requester within 60 days of each meeting.

IV. Paperwork Reduction Act of 1995

This notice refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information resulting from formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0429. The collection of information in 21 CFR part 312 (INDs) has been approved under OMB control number 0910–0014.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08010 Filed 4–16–18; 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; Submission for Office of Management and Budget Review; 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, we, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

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

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), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (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) (21 CFR 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) (21 CFR 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(a), 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) (21 CFR 606.145(c)) requires transfusion services to notify certain blood collection establishments concerning bacterial contamination of platelets and other additional information. 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 brief, requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121 (21 CFR 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.

Section 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) (21 CFR 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 brief, §§ 610.46 and 610.47 (21 CFR 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)). The burden for the recordkeeping requirements under §§ 610.46(a) and (b) and 610.47(a) and

(b) are included under § 606.100 (21 CFR 606.100).

Section 630.40(a) (21 CFR 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) (21 CFR 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) (21 CFR 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 (21 CFR 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 (21 CFR 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 (21 CFR 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) (21 CFR 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) (21 CFR 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, the regulations in 21 CFR part 630 that include requirements for blood and blood components intended for transfusion or further manufacturing use and in 21 CFR part 640 that require additional standards for certain blood and blood products are as follows: 21 CFR 630.5(b)(1)(i) and(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); 640.21(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); 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, recordkeeping, and disclosure 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 will test reactive by a screening test for syphilis and be 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 ($3{,}021 \times 3$) 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 ($3{,}021 \times 3$) 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 (a)(3), collecting establishments would notify the consignee two times for each of the 20,397 ($6{,}799 \times 3$ components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 40,794 ($20{,}397 \times 2$) 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)(x), 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. In addition, FDA estimates that there would be only three notifications for requalification of donors under § 630.35(b). FDA also estimates the average time 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.

In the **Federal Register** of January 23, 2018 (83 FR 3165), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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	0.5 (30 min)	23
606.151(e)	[5] 363	12	4,356	0.08 (5 min.)	348
606.160 [4]	[5] 363	1,055.096	383,000	0.75 (45 min.)	287,250
606.160(b)(1)(viii) HIV consignee notification	1,734	10.4533	18,126	0.17 (10 min.)	3,081
	4,961	3.6537	18,126	0.17 (10 min.)	3,081
606.160(b)(1)(viii) HCV consignee notification	1,734	23.5259	40,794	0.17 (10 min.)	6,935
	4,961	8.2229	40,794	0.17 (10 min)	6,935
HIV recipient notification	4,961	0.3538	1,755	0.17 (10 min.)	298
HCV recipient notification	4,961	0.4132	2,050	0.17 (10 min.)	349
606.160(b)(1)(x)	2,303	734.6939	1,692,000	0.05 (3 min.)	84,600
606.160(b)(1)(xi)	1,734	0.8137	1,411	0.05 (3 min.)	71
606.165	[5] 363	1,055.096	383,000	0.08 (5 min.)	30,640
606.170(a)	[5] 363	12	4,356	1	4,356
610.40(g)(1)	2,303	1	2,303	0.5 (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, 610.46(a) and (b), 610.47(a) and (b), 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 disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
606.145(c)	4,961	0.2822	1,400	0.02	28
606.170(a)	[2] 363	12	4,356	0.5 (30 min.)	2,178
610.40(c)(1)(ii)	2,303	0.0595	137	0.08 (5 min.)	11
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	15	12	180	0.20 (12 min.)	36
610.40(h)(2)(vi)	2,303	3.28	7,554	0.08 (5 min.)	604
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,734	5.2266	9,063	0.17 (10 min.)	1,541
610.46(a)(3)	1,734	5.2266	9,063	0.17 (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	0.17 (10 min.)	3,467
610.47(a)(3)	1,734	11.7630	20,397	0.17 (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	0.08 (5 min.)	34,320
630.40(a) [4]	81	50	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: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07972 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold a public meeting.

DATES: Thursday, May 3, 2018, from 8:30 a.m. to 5:00 p.m. and Friday, May 4, 2018, from 8:30 a.m. to 2:00 p.m. ET.

ADDRESSES: The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857, Room 5E29. The conference call-in number: 1–800–857–9729 and Passcode: 1318150. The webinar link is *https://hrsa.connectsolutions.com/actpcmd.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACTPCMD should contact Dr. Kennita R. Carter, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Dr. Kennita R. Carter, DFO, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Room 15N–116, Rockville, MD 20857; (2) call 301–945–3505; or (3) send an email to *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of the Department of Health and Human Services on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service Act (PHSA). ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. The Committee also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHSA, and recommends appropriation levels for programs under this Part.

During the May 3–4, 2018, meeting, ACTPCMD will review the impact of the Title VII, Section 747 and oral health training programs, and make recommendations on funding and appropriation levels. In addition, the Committee will identify its strategic priorities for the coming year, and discuss issues related to pending Committee reports on the integration of behavioral health into primary care and oral health training, and clinical trainee and faculty well-being and resilience. Information about ACTPCMD and the agenda for this meeting is located on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.* Please note that agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACTPCMD should be sent to Dr. Carter, DFO, using the contact information above at least three business days prior to the meeting.