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, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by July 26, 2021.

AGENCY: Food and Drug Administration, HHS.

I. Background

In the Federal Register of May 13, 2021 (86 FR 26224), FDA published a notice entitled “Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use,” which announced the initiation of a public scoping period that would end on June 14, 2021, and noted that comments on scoping would need to be submitted prior to the close of this period. In response to a request submitted to the docket, FDA is reopening the comment period for public scoping on the EIS for an additional 30 days, until July 14, 2021. The Agency believes that a 30-day extension will allow adequate time for interested persons to submit comments without significantly delaying publication of the draft EIS.

II. Electronic Access

Persons with access to the internet may obtain the notice of intent through the Agency’s weblink “Environmental Impact Statement (EIS) for Certain Sunscreen Drug Products,” available at https://www.fda.gov/drugs/guidance-compliance-regulatory-information or by searching for the above docket number at https://www.regulations.gov.

Dated: June 21, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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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 of certain information that may require immediate corrective action. Respondents to this collection of information include 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 submission data, 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 our experience with the information collection. We estimate 3.5 million donations of Source Plasma from approximately 2.5 million donors and 12.3 million donations of Whole Blood and apheresis Red Blood Cells, including an estimated 10,000 (approximately 0.081 percent of 12.3 million) autologous donations, from 9 million donors. Assuming each autologous donor makes an average of 1.1 donations, we estimate there are 9,090 autologous donors (10,000 autologous/1.1 average donations).

We estimate 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(e)(1)(ii) (21 CFR 610.40(e)(1)(ii)). Under § 610.40(g)(2) and (b)(2)(i)(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 a review of data, FDA receives less than one application per year from manufacturers of Source Leukocytes; however, we estimate one annually for this analysis. Also according to Agency data, there are approximately 15 licensed manufacturers that ship known reactive human blood or blood components under § 610.40(b)(2)(ii)(C) and (D). We estimate each manufacturer would ship an average of 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)(iii)(C) and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(iii)(D).

Based on information received from industry, we estimate 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 the 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) (21 CFR 610.42(a)), we estimate that the warning statement would be necessary no more than once a year.

We estimate 3,100 repeat donors will test reactive on a screening test for HIV. We assume an average of three components was made from each donation. Under § 610.46(a)(1)(ii)(B) and (a)(3) (21 CFR 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 4,961 consignees will be required under § 610.46(b)(3) to notify transfusion services because of failure to satisfy 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 6,800 repeat donors per year would test reactive for antibody to HCV. Under §§ 610.47(a)(1)(ii)(B) and (a)(3) (21 CFR 610.47(a)(1)(ii)(B) and (a)(3)), collecting establishments would notify the consignee two 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 assume 4,961 consignees 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 donation. Based on 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 one-third, or 869 of the 2,606 blood collecting establishments, would need to provide, under §630.40(a) (21 CFR 630.40(a)), additional information and onsite counseling to the estimated 848,000 (one-third of approximately 2,544,000) ineligible donors.

We estimate another 0.6 percent of 14,018,000 potential donors (84,108 donors) are deferred annually based on test results. We assume 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 their 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 their 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 assume 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.

We assume 95 percent of recordkeepers, which account for 99 percent of blood donations, 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) (21 CFR 606.160(b)(1)(ix)), we assume a total number of annual records based on 2,544,000 ineligible donors 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)(ix), 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 (21 CFR 610.41), which in turn will lead to the notification of their referring physicians. Under §610.41(b), we estimate 25 submissions for requalification of donors each requiring 7 hours per submission. In addition, we assume that there would be only three notifications for requalification of donors under §630.35(b) (21 CFR 630.35(b)), which would also require 7 hours for each submission.

An 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 February 22, 2021 (86 FR 10582), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. On our own initiative, however, and for efficiency of Agency operations, we are revising the information collection to include and consolidate related information collection found in Agency guidance. The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We are revising the information collection to reference the Agency guidance document entitled “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion” (December 2020), which provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion. The guidance is available for download from our website at: https://www.fda.gov/media/123448/download.

The guidance recommends blood collection establishments notify transfusion services if a distributed platelet product is subsequently identified as positive for bacterial contamination and that blood establishments communicate to their consignees the type of storage container the platelets are stored in. We assume such notification is a usual and customary business practice for blood establishments and, therefore, estimate no burden estimate for the information collection.

We also developed the guidance entitled “Labeling of Red Blood Cell Units with Historical Antigen Typing Results” (December 2018) to provide establishments that collect blood and blood components for transfusion with recommendations for labeling Red Blood Cell units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The guidance is available for download from our website at: https://www.fda.gov/media/119376/download.

The guidance recommends disclosing non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label. We assume such information disclosures would be usual and customary for blood establishments and, therefore, estimate no burden for the information collection, currently approved under OMB control number 0910–0862.

We estimate the burden of this collection of information as follows:

<table>
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<th>21 CFR section; activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
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</table>

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).
We have adjusted our burden estimate for this information collection since last OMB review to reflect an overall increase of 79,024 hours annually. We attribute this adjustment to an increase in the number of registered blood establishments over the last 3 years.

Dated: June 21, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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