TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued
[Nonregistered non-licensed commercial feed mills] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	4,357	1	4,357	4	17,428
225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	4,357	96	418,272	0.12 (7 minutes)	50,193
225.202 requires records of formulation, production, and distribution of medicated feeds.	4,357	260	1,132,820	0.65 (39 minutes)	736,333
Total					821,382

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Nonregistered non-licensed mixer/feeders] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142 requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.	3,400	4	13,600	1	13,600
225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	3,400	1	3,400	4	13,600
225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	3,400	32	108,800	0.12 (7 minutes)	13,056
225.202 requires records of formulation, production, and distribution of medicated feeds.	3,400	260	884,000	0.33 (20 minutes)	291,720
Total					331,976

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

Our estimated burden for the information collection reflects an overall decrease of 10,435 hours and an increase of 831,545 records since the last OMB approval. We attribute this adjustment due to an increase in the number of non-registered, non-licensed commercial medicated feed mills and decrease in non-licensed medicated feed mill recordkeeping the last few years.

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15487 Filed 7–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0343]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 August 21, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

OMB Control Number 0910–0116—Revision

The FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulatory oversight of the U.S. blood supply. FDA issues and enforces requirements for blood collection and for the manufacturing of blood products, including both blood components intended for transfusion or for further manufacturing use. To implement applicable statutory provisions, regulations are codified at 21 CFR part 606—Current Good Manufacturing Practice for Blood and Blood Components; 21 CFR part 610—General Biological Products Standards; 21 CFR part 630—Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use; and 21 CFR part 640—Additional Standards for Human Blood and Blood Products. The regulations establish quality standard requirements applicable to blood and blood products including information collection provisions.

CBER works closely with other parts of the Department of Health and Human Services to identify and respond to potential threats to blood safety and to monitor the availability of the blood supply. FDA has progressively strengthened the overlapping safeguards that help to ensure donor health and the safety of the blood supply for recipients of blood and blood products. For example:

- Blood donors answer medical history questions to identify risk factors that could indicate possible infection with a relevant-transfusion transmitted infection.
- FDA requires blood establishments to maintain a record of deferred donors to prevent collections from ineligible donors.
- Blood donations are tested for several relevant transfusion-transmitted infections, including HIV, hepatitis B virus, and hepatitis C virus.

FDA also inspects blood establishments and monitors reports of errors, accidents, and adverse events associated with blood donation or transfusion.

Description of Respondents: Respondents to the collection of information are licensed and registered-only establishments that collect blood and blood components intended for transfusion or further manufacturing use.

For operational efficiency, we are revising the information collection to account for burden that may be attributable to recommendations found in associated FDA guidance documents, as listed below, and currently approved in OMB control number 0910–0681. FDA regulations in § 630.3(h) (21 CFR 630.3(h)) set forth a list of relevant transfusion-transmitted infections (RTTIs) (§ 630.3(h)(1)) and the conditions under which a TTI would meet the definition of an RTTI (§ 630.3(h)(2)). We developed Agency guidance documents, consistent with our good guidance practice regulations in 21 CFR 10.115, that provide for comment at any time. These guidance documents include recommendations specific to certain RTTI or TTI regarding the collection of blood and blood components and discuss corresponding recordkeeping and/or notification activities. The guidance documents are available for download from our website at *https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.*

A. Guidances Recommending Notification Based on Reactive Test Results

The following guidance documents provide recommendations for consignee and physician notification relating to donations that test reactive for an RTTI:

- Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009);
- Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry (December 2017);
- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry (May 2019); and
- Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II); Guidance for Industry (February 2020).

B. Guidances Recommending Notification Based on Post Donation Information Regarding a Risk Factor or History of an RTTI or TTI

The following guidance documents provide recommendations for consignee and, in some instances, physician notification under circumstances where a blood establishment may receive information following collection that reveals the donor had a history of or risk factor for an RTTI or TTI at the time of collection and should have been deferred for the risk factor:

- Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry (January 2017);
- Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry (May 2022); and
- Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry (December 2022).

In the **Federal Register** of February 21, 2023 (88 FR 10515), we 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 information collection topics solicited. On our own initiative we have since revised the information collection to reflect recent finalization of the guidance document entitled ''Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products,'' announced in the **Federal Register** of May 12, 2023 (88 FR 30765). The recommendations included in the guidance document will potentially expand the number of people eligible to donate blood, while also maintaining the appropriate safeguards to protect the safety of the blood supply.

We believe the notifications discussed in the respective guidance documents are rare and that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. We also believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for an RTTI or TTI. However, to account for burden among respondents that may be attributable to the notification activity we allot one response and 1 hour annually. As additional guidance is developed by FDA addressing other RTTIs under § 630.3(h)(2), we will modify the information collection accordingly.

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15458 Filed 7–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–D–4417, FDA–2013–N–1619, FDA–2018–D–2613, FDA–2021–N–0341, FDA–2016–N–2066, FDA–2022–N–0862, and FDA–2022–N–1874]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Medical Gases and Active Pharmaceutical Ingredients)	0910–0139	6/30/2026
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	0910–0606	6/30/2026
Prescription Drug Advertisements	0910–0686	6/30/2026
Federal-State Food Regulatory Program Standards	0910–0760	6/30/2026
Certification of Identity for Freedom of Information and Privacy Act Requests	0910–0832	6/30/2026
The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 (Outcomes Study)	0910–0915	6/30/2026
Perceptions of Prescription Drug Products with Medication Tracking Capabilities	0910–0916	6/30/2026

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15456 Filed 7–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Mpox Vaccine Distribution Request Forms, OMB No. 0915–xxxx–New

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 21, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3093.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Mpox Vaccine Distribution Request Forms, OMB No. 0915–xxxx–New.

Abstract: On August 4, 2022, the mpox outbreak was declared a public health emergency (PHE) in the United States. From the outset, HRSA engaged with federal partners across HHS to provide resources to combat the spread of mpox; assist health care providers who are treating people who have mpox; and ensure those who are most at risk are the focus of vaccine response efforts.

HHS authorized HRSA to receive allotments of the JYNNEOS vaccine for mpox for rapid distribution to Ryan White HIV/AIDS Program (RWHAP) recipients. HRSA was identified as a distribution partner due to the health care services provided to individuals with HIV and the number of uninsured and underinsured persons seen in RWHAP and Health Center Programs. The allotments were meant to supplement, not replace, vaccine efforts at jurisdictional levels.

To expedite dispensing of the vaccine, HRSA provided the vaccine to dually funded RWHAP Part C and Health Center providers that care for at-risk populations. Most of the identified providers already had access to the Health Partner Ordering Portal (HPOP),