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

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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),

a system HHS uses to quickly distribute vaccines to HHS health partners. For providers who elected to receive the vaccine but did not have access to HPOP, HRSA registered them in the HPOP system. HRSA made 73 shipments to 57 (53 dually funded and four Part C only) RWHAP recipients who elected to receive and distribute the mpox vaccine.

RWHAP recipients that receive shipments of the JYNNEOS vaccine are required to upload administration and inventory/wastage data into HPOP on a weekly basis. The information collected includes federal or state PIN, contact, lot number, description, number of vials, expiration date, courses/doses/bottles administered, bottles available, wastage, reason, and date reported.

RWHAP recipients who accept JYNNEOS vaccine from HRSA are also asked to submit data with information necessary for HRSA to assess the quantity of mpox vaccines requested and their distribution status. The information collected includes grant number; recipient name, point of contact, and phone number; shipping address; shipping point of contact, email address, and phone number; and number of boxes of mpox vaccine requested.

As a result of the PHE for mpox, the Assistant Secretary for Planning and Evaluation issued a Paperwork Reduction Act waiver for collection of these data. Since the PHE ended on January 31, 2023, HRSA is proposing to continue collecting these data until December 31, 2025. This action will help to improve HRSA's ability to provide additional resources and assistance to RWHAP recipients, which may result in increased prevention of mpox among RWHAP clients.

A 60-day notice was published in the **Federal Register** on May 9, 2023, vol. 88, no. 89, pp. 29909–10. There was one comment received. There are no changes made to the information collection since the comment received is outside the scope of this information request.

Need and Proposed Use of the Information: HRSA will use the information collected to (1) assess and improve its response to the mpox outbreak and (2) improve HRSA's ability to provide resources and assistance to RWHAP recipients in future public health emergencies.

Likely Respondents: Dually funded RWHAP Part C and Health Center recipients who accepted at least one shipment of mpox vaccine from HRSA.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Vaccine Distribution Report	57	1	57	0.20	11.40
Wastage Upload Report	57	52	2,964	0.23	681.72
Therapeutic Courses (Administered and Available)	57	52	2,964	0.23	681.72
Total	171				1,374.84

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–15463 Filed 7–20–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Caspase Inhibitors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to Elgia Therapeutics Inc. (''Elgia''), headquartered in La Jolla, CA.

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences' Office of Strategic Alliances on or before August 7, 2023 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: (301) 642–0460; Email: *sury.vepa@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Application No. 61/299,790, filed January 29, 2010 which is entitled ''Caspase Inhibitors'' (HHS Ref. No. E–308–2009–0–US–01);

2. International Patent Application No. PCT/US2011/02274 filed on January 27, 2011 which is entitled ''Caspase Inhibitors'' (HHS Ref. No. E–308–2009–0–PCT–02); and

3. US Patent Application No. 13/575,273 filed on July 25, 2012 which is entitled ''Caspase Inhibitors'' and issued as U.S. Patent No. 9,365,612 (HHS Ref. No. E–308–2009–0–US–03).

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

''Development, manufacture, use and commercialization of Caspase Inhibitors