by wildland fire smoke include [NIOSH 2023]:

- Symptoms such as eye irritation, sore throat, wheeze, and cough
- Asthma and chronic obstructive pulmonary disease (COPD) exacerbations
- Bronchitis and pneumonia
- Adverse birth outcomes
- Cardiovascular (heart and blood vessel) outcomes

Long work shifts and physical demands of the work performed (resulting in higher breathing rates) may impact a worker's exposures and health response to wildland fire smoke. Still, the scientific community does not fully understand how long-term, repeated exposures, or other exposures to wildland fire smoke may affect a worker's health. Additionally, very little is known about how exposure to many different compounds at the same time, including compounds released from the burning of man-made materials (such as those found in the wildland-urban interface), may affect a worker's health.

NIOSH plans to review and assess the available scientific evidence to support the development of recommendations to protect outdoor workers from wildland fire smoke. NIOSH currently recommends that employers be aware that exposure to wildland fire smoke may adversely affect the health of their workforce and be prepared to take action to limit their workers' exposures when a wildfire has emitted smoke in and around their work environment [NIOSH 2023].

It is also currently recommended that employers and workers prepare for and plan to implement procedures to reduce exposures to smoke when necessary [NIOSH 2023]. As NIOSH continues to review and assess the scientific literature, recommendations will be developed and updated as necessary. Additional information and recommendations are available on the NIOSH Safety and Health Topic Page on Outdoor Workers Exposed to Wildfire Smoke (*https://www.cdc.gov/niosh/topics/firefighting/wffsmoke.html*). NIOSH will update this Topic Page and recommendations as necessary to be consistent with the assessment of the information obtained from this RFI and the development of the hazard review.

To reiterate, this RFI is intended to announce the opportunity for the public to provide NIOSH with information about approaches to assess and control the hazards of wildland fire smoke to outdoor workers to inform the development of a hazard review document. Scientific information related to wildland fire smoke is requested on the following topics:

- Properties and characteristics of wildland fire smoke mixtures
- Potential for occupational exposures to outdoor workers
- Health effects of exposures
- Outdoor worker populations at risk
- Exposure monitoring
- Risk management and control
- Research needs.

Reference

NIOSH [2023]. Outdoor workers exposed to wildfire smoke. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, *https://www.cdc.gov/niosh/topics/firefighting/wffsmoke.html.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2024–05403 Filed 3–13–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–0953; Docket No. CDC–2024–0016]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery. The information collection activities provide a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal Government's commitment to improving service delivery.

DATES: CDC must receive written comments on or before May 13, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0016 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who

are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 0920–0953, Exp. 10/31/2024)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The information collection activities associated with this collection serve to provide a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal Government's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable. CDC will only submit a collection for approval under these generic clearances if they meet the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based) on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are noncontroversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under CDC generic clearances provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made; the sampling frame; the sample design (including stratification and clustering); the precision requirements or power calculations that justify the proposed sample size; the expected response rate; methods for assessing potential nonresponse bias; the protocols for data collection; and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

CDC requests OMB approval for an estimated 13,075 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Type of collections	Number of respondents	Annual frequency per response	Hours per response	Total hours
Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.	Print Surveys	50,000	1	15/60	12,500
	Focus Groups	100	1	2	200
	Online Surveys	1500	1	15/60	375
Total					13,075

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–05386 Filed 3–13–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict Review.

Date: June 13, 2024.

Time: 1 p.m.–4 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone: (304) 285–5951; Email: *MGoldcamp@cdc.gov.*

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–05458 Filed 3–13–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5323]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of Two New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on December 18, 2023. The document announced the withdrawal of approval of two new drug applications (NDA), withdrawn as of January 17, 2024. The document indicated that FDA was withdrawing approval of NDA 022424, FLOWTUSS (guaifenesin 200 milligrams (mg)/5 milliliters (mL) and hydrocodone bitartrate 2.5 mg/5 mL) Oral Solution held by Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920. Before FDA withdrew the approval of this NDA, Chartwell RX Sciences, LLC informed FDA that it did not want the approval of the NDA withdrawn. Because Chartwell RX Sciences, LLC timely requested that approval of NDA 022424 not be withdrawn, the approval is still in effect. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, December 18, 2023 (88 FR 87433), appearing on page 87433 in FR Doc. 2023–27661, the following correction is made:

On page 87433, in the table, the entry for NDA 022424 is removed.

Dated: March 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05426 Filed 3–13–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–1620 and FDA–2023–E–1597]

Determination of Regulatory Review Period for Purposes of Patent Extension; PYRUKYND

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PYRUKYND and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by May 13, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 10, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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