information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessing Adoption and Implementation of the National Institute of Occupational Safety and Health's (NIOSH) Outputs—New—National Institute of Occupational Safety and Health's (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a new Generic information collection for a period of three years under the project titled, ''Assessing Adoption and Implementation of the National Institute of Occupational Safety and Health's (NIOSH) Outputs.''

With the continuation of the Government Performance and Results Act and the more recent passage of the Foundations of Evidence-Based Policy Making Act, there is an increased need for federal agencies to measure and demonstrate their impact. However, measuring impact is challenging, especially for organizations that have a science-driven mission because of the time it takes to move from basic to applied research. Demonstrating attribution (cause and effect relationships) is particularly challenging for research organizations.

NIOSH research is often designed to collect implementation and adoption data through document reviews of NIOSH records, including grantee final reports, and through interviews with NIOSH researchers (federal employees). While commonly recognized metrics, these data sources are not comprehensive, representative, or informative of the adoption and implementation of NIOSH products and efforts. Further, the design and execution of research projects has hindered research and program leaders prioritizing information collections to understand and assess the adoption and implementation of research efforts and products.

The proposed generic information collection package would allow researchers to expeditiously pursue efforts to provide NIOSH with critical information to inform mission-driven needs. Additionally, the proposed efforts go beyond simply measuring customer satisfaction and rather seek to advance NIOSH's burden, need, and impact framework for future research while also endeavoring to execute the Office of Management and Budget's (OMB) guidance regarding the Foundations of Evidence-Based Policymaking Act.

Respondents are expected to consist of users and potential users of NIOSH products including subject matter expects, former NIOSH funding recipients, and intermediary and end users. CDC requests OMB approval for an estimated 17,150 total burden hours with an estimated annual burden of 6,069 hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of respondent	Type of data collection instrument	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Subject matter experts	Survey instrument (single, pre and post, or poll) including demographics.	5,000	1	20/60
	Informed consent form	250	1	5/60
	Interview or focus group guide	250	1	1
Former NIOSH funding recipients	Survey instrument (single, pre and post, or poll) including demographics.	200	1	20/60
	Informed consent form	25	1	5/60
	Interview or focus group guide	25	1	1
Intermediary or end users (e.g., employers, workers, manufactures, labor/professional associations, policymakers).	Survey instrument (single, pre and post, or poll) including demographics.	10,000	1	20/60
	Informed consent form	650	1	5/60
	Interview or focus group guide	650	1	1

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. 2024–23859 Filed 10–15–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–4163]

Determination That NOXAFIL (Posaconazole) Delayed-Release Tablets, 100 Grams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that NOXAFIL (posaconazole) delayed-release tablets, 100 grams (g), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NOXAFIL (posaconazole) delayed-release tablets, 100 g, is the subject of NDA 205053, held by Merck Sharp & Dohme Corp., and initially approved on November 25, 2013. Noxafil delayed-release tablets are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. In addition, NOXAFIL is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with graft-versus-host disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows; for NOXAFIL delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kilograms.

NOXAFIL (posaconazole) delayed-release tablets, 100 g, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Aizant Drug Research Solutions Private Limited, submitted a citizen petition dated September 2, 2024 (Docket No. FDA–2024–P–4163), and amended on September 4, 2024, under 21 CFR 10.30, requesting that the Agency determine whether NOXAFIL (posaconazole) delayed-release tablets, NDA 205053 was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NOXAFIL (posaconazole) delayed-release tablets, 100 g, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NOXAFIL (posaconazole) delayed-release tablets, 100 g, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NOXAFIL (posaconazole) delayed-release tablets, 100 g, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NOXAFIL (posaconazole) delayed-release tablets, 100 g, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23811 Filed 10–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0281]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 15, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0281–30D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Prevention Communication Formative Research.

Type of Collection: Extension.

OMB No: 0990–0281—Office of Disease Prevention and Health Promotion.

Abstract: The Office of Disease Prevention and Health Promotion (ODPHP) is focused on developing and disseminating health information to the public. ODPHP faces an increasingly urgent interest in finding effective ways to communicate health information to