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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

America's diverse population. ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels, from print to new communication technologies. To carry out prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of their communication and education efforts. The information collected will be used to improve communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Food Is Medicine, Physical Activity Guidelines for Americans, MyHealthfinder, the Move Your Way® Campaign, the President's Council on Sports, Fitness & Nutrition, health literacy and healthy aging. ODPHP communicates through its website (*www.health.gov*) and through other channels including social media, print materials, interactive training modules, and reports. This request builds on previous formative research approaches to place more emphasis on Web-based data collection to allow greater geographical diversity among respondents, to decrease respondent burden, and to save government costs. Data collection will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public's understanding of disease prevention and health promotion content, responses to prototype materials, and barriers to effective use.

The program is requesting a 3-year extension of its clearance.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
In-depth interviews—Screener	500	1	10/60	83
In-depth interviews—Instrument	167	1	1.00	167
Focus groups—Screener	975	1	10/60	162.5
Focus groups—Instrument	325	1	1.50	487.5
Intercept interviews	1750	1	5/60	146
Cognitive testing of instruments—Screener	50	1	10/60	8
Cognitive testing of instruments—Cognitive test	17	1	2.00	34
Web-based surveys—Screener	10,000	1	5/60	833
Web-based surveys—Survey	3,333	1	15/60	833
Omnibus surveys	700	1	10/60	117
Gatekeeper reviews	109	1	30/60	54
Card sorting—Screener	200	1	10/60	33
Card sorting—Card sort	67	1	1.00	67
Usability and prototype testing of materials (print and web)—Screener	600	1	10/60	100
Usability and prototype testing of materials (print and web)—usability tests	208	1	1.00	208
Total	.....	.....	.....	3,333

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–23795 Filed 10–15–24; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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. 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: Center for Scientific Review Special Emphasis Panel; Basic Biology of Blood, Heart, and Vasculature.

Date: November 7, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Aisha Lanette Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3527, *aisha.walker@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: November 7–8, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4152, MSC 7846, Bethesda, MD 20892, (301) 827–6009, *lin.reigh-yi@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; S10 Instrumentation: Flow Cytometry.

Date: November 7, 2024.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3717, *jessica.smith6@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Pathogenic Eukaryotes.

Date: November 7, 2024.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.