issued on February 4, 2020 (85 FR 6201) (2020 draft guidance). In revising this guidance, FDA considered comments received on the 2020 draft guidance and expanded the scope of the 2020 draft guidance to fulfill the BsUFA III commitment to publish draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products. Changes from the 2020 draft guidance include additional recommendations and an example for interchangeable biosimilar products. In addition, editorial changes were made to improve clarity.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in FDA's guidance entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format: Promotional Labeling and Advertising Materials for Human Prescription Drugs,'' the collections of information in 21 CFR part 314, and the collections of information resulting from submissions using Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 202.1 have been approved under OMB control number 0910–0686; the collections of information in FDA's guidance entitled ''Medical Product Communications That Are Consistent With the Food and Drug Administration Required Labeling: Questions and Answers'' have been approved under OMB control number 0910–0856; the collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303; and the collections of information relating to section 351(k) of the Public Health Service Act relating to biosimilar and interchangeable product applications have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08886 Filed 4–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0477]

Agency Information Collection Revision 60-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.

DATES: Comments on the ICR must be received on or before June 24, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0477–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 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: Incident Report Form.

Type of Collection: Reinstatement with Change.

OMB No.: 0990–0477.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting reinstatement of the OMB No. 0990–0477, Incident Report Form, with two new information elements on the Incident Report form: *IORG # for Reviewing IRB;* and, *Revising research policies and procedures* as a corrective action plan category, if it applies. The purpose of the Incident Report form is to facilitate organizations or institutions prompt reporting of specific human subject protection incidents to OHRP, in a simplified standardized format, as required by HHS protection of human subjects regulations at 45 CFR part 46.

ANNUALIZED BURDEN HOUR TABLE

Forms name	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Incident Report	25	1	30/60	12.5
Incident Report	25	3	30/60	37.5
Incident Report	200	5	30/60	500
Total				550

Sherrette A. Funn,

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

[FR Doc. 2024–08799 Filed 4–24–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Committee on Minority Health; Notice of Meeting Cancellation

The Office of Minority Health (OMH) published a notice in the **Federal Register** concerning a meeting of the Advisory Committee on Minority Health. The meeting scheduled for Tuesday, April 30, 2024 at 11 a.m. to 12:30 p.m. (EDT) is cancelled. The notice for the April 30, 2024 meeting was published in the **Federal Register** on Monday, April 1, 2024 in FR Doc. 2024–06850, on pages 22412–22413.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, OMH's Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Telephone: (240) 453–6816; Email: *OMH-ACMH@hhs.gov.*

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2024–08896 Filed 4–24–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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. 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: National Institute of Environmental Health Sciences Special Emphasis Panel: Superfund Hazardous Substances Research and Training Program (SRP) Conflict Panel Review.

Date: May 30–31, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, 530 Davis Drive, Keystone Building, Durham, NC 27713 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (984) 287–3340, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 19, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08832 Filed 4–24–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/watch=54495*

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. 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: National Advisory Council for Nursing Research.

Date: May 23, 2024.

Open: May 23, 2024, 9:00 a.m. to 4:15 p.m.

Agenda: Call to Order and Opening Remarks, NINR Director's Report, Discussion of NINR Programs, Council Open Discussion.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 6C6, Bethesda, MD 20892 (Hybrid Meeting).

Closed: May 23, 2024, 4:15 p.m. to 4:45 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 6C6, Bethesda, MD 20892.

Contact Person: Elizabeth Tarlov, Ph.D., RN Director, Division of Extramural Science Programs (DESP), National Institute of Nursing Research, 31 Center Drive, Bethesda, MD 20892, (301) 594–1580, *elizabeth.tarlov@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of an organization may submit a letter of intent, a brief description of the organization represented and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://www.ninr.nih.gov/aboutninr/nacnr,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: April 22, 2024.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08889 Filed 4–24–24; 8:45 am]

BILLING CODE 4140–01–P