• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–1145 for ''Enrichment Strategies for Clinical Trials to Support Demonstration of Effectiveness of Human Drugs and Biological Products; Guidance for Industry; Availability. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4212, Silver Spring, MD 20993–0002, 301–796–2270; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Enrichment Strategies for Clinical Trials to Support Demonstration of Effectiveness of Human Drugs and Biological Products.'' This document provides guidance to industry on enrichment strategies that can be used in clinical trials intended to demonstrate effectiveness (and in some cases safety) of human drugs and biological products. This guidance finalizes the draft guidance entitled ''Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products'' issued on December 17, 2012 (77 FR 74670). Changes made to the guidance took into consideration comments received related to discussions of study design and analysis, specific patient populations to be studied, and genomic strategy considerations. In addition, editorial changes were made, primarily, for clarification and elimination of redundancies. Although the draft guidance was issued by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health, upon consideration, the finalized guidance is being issued by CDER and CBER only because the topics covered pertain mostly to studies conducted for products regulated by these two centers.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Enrichment Strategies for Clinical Trials to Support Demonstration of Effectiveness of Human Drugs and Biological Products.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively, and the collection of information resulting from prescription drug product labeling is approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: March 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04815 Filed 3–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Y–12 Plant in Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

On February 26, 2019, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Y–12 Plant in Oak Ridge, Tennessee, during the period January 1, 1958, through December 31, 1976, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on March 28, 2019, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health.

[FR Doc. 2019–04824 Filed 3–14–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, March 29, 2019, 08:00 a.m. to March 29, 2019, 05:00 p.m., National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on February 07, 2019, 84 FR 2551.

This meeting is being amended to change the date of the meeting from March 29, 2019 to April 1, 2019. This meeting is closed to the public. The meeting is closed to the public.

Dated: March 12, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–04853 Filed 3–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Panel-Tumor Glycomics.

Date: April 11, 2019.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W260 Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer Special Review Branch Division of Extramural Activities National Cancer Institute, NIH 9609 Medical Center Drive, Room 7W108 Bethesda, MD 20892–9750 240–276–6343 *schweinfestcw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–04851 Filed 3–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: May 20–21, 2019.

Closed: May 20, 2019, 1:00 p.m. to adjournment.

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

Place: National Institutes of Health, 6710B Rockledge Drive, Conference Rooms 1425–1427, Bethesda, MD 20892.

Open: May 21, 2019, 8:00 a.m. to 2:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, 6710B Rockledge Drive, Conference Rooms 1425–1427, Bethesda, MD 20892.

Contact Person: Dr. Joyce A. Hunter, Deputy Director, NIMHD, National Institutes of Health, National Institute on Minority