Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9291, email: *gail.schmerfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' Prescription opioid analgesics are an important component of modern pain management. However, abuse and misuse of these drug products have created a serious and growing public health problem. One important step toward the goal of creating safer opioid analgesics has been the development of opioid drug products that are formulated to deter abuse. FDA considers the development of these products a high public health priority. It is important that generic versions of opioids that reference listed drugs whose labeling describes abuse-deterrent properties are available to help ensure availability of analgesics for patients who need them.

For FDA to approve an abbreviated new drug application (ANDA), the Agency must find, among other things, that the generic drug product has the same active ingredient(s), dosage form, route of administration, strength, and, with limited exceptions, labeling as the reference listed drug (RLD); is bioequivalent to its RLD; that the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are adequate to assure and preserve its identity, strength, quality, and purity; and that the inactive ingredients and composition of the generic drug are not unsafe for use under the conditions prescribed, recommended, or suggested in the labeling (see, *e.g.,* the Federal Food, Drug, and Cosmetic Act (the FD&C Act) 505(j)(2)(A) and (j)(4) (21 U.S.C. 355(j)(2)(A) and (j)(4))). FDA classifies as ''therapeutically equivalent'' those products that meet the following general criteria: (1) They are approved as safe and effective; (2) they are pharmaceutical equivalents in that they: (a) Contain identical amounts of the same active ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; and (5) they are manufactured in compliance with current good manufacturing practices regulations. (See preface of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book).) FDA believes that a product classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the reference product.

Accordingly, if the RLD's labeling describes abuse-deterrent properties, the ANDA applicant should evaluate its product to show that it is no less abuse-deterrent than the RLD with respect to all potential routes of abuse. Marketing a generic opioid drug product that is less abuse-deterrent than the RLD could lead opioid abusers to preferentially seek out and abuse generics.

This draft guidance describes FDA's current thinking about the studies that should be conducted by a potential ANDA applicant and submitted to FDA in an ANDA to demonstrate that a generic solid oral opioid drug product is no less abuse-deterrent than its RLD with respect to all potential routes of abuse.

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 the principles for evaluating the abuse-deterrence of generic solid oral opioid drug 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.

FDA intends to hold a public meeting following the close of the comment period to discuss further the evaluation of the abuse deterrence of generic opioid drug products and related issues, as appropriate. Further details will follow in a notice of public meeting published in the **Federal Register**.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06766 Filed 3–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Fitness, Sports, and Nutrition

AGENCY: President's Council on Fitness, Sports, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Council on Fitness, Sports, and Nutrition (PCFSN) will hold its annual meeting. The meeting will be open to the public.

DATES: The meeting will be held on May 16, 2016, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW., Great Hall, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Shellie Pfohl, Executive Director, Office of the President's Council on Fitness, Sports, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567. Information about PCFSN, including details about the upcoming meeting, can be obtained at *www.fitness.gov.*

SUPPLEMENTARY INFORMATION: The primary functions of the PCFSN include (1) advising the President, through the Secretary, concerning progress made in carrying out the provisions of Executive Order 13545 and recommending to the President, through the Secretary, actions to accelerate progress; (2) advising the Secretary on ways to promote regular physical activity, fitness, sports

participation, and good nutrition. Recommendations may address, but are not necessarily limited to, public awareness campaigns; federal, state, and local physical activity; fitness, sports participation, and nutrition initiatives; and partnership opportunities between public- and private-sector health promotion entities; (3) functioning as a liaison to relevant state, local, and private entities in order to advise the Secretary regarding opportunities to extend and improve physical activity, fitness, sports, and nutrition programs and services at the local, state, and national levels; and (4) monitoring the need to enhance programs and educational and promotional materials sponsored, overseen, or disseminated by the Council, and shall advise the Secretary, as necessary, concerning such need. In performing its functions, the Council shall take into account the Federal Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans.

The PCFSN will hold, at a minimum, one meeting per fiscal year. The meeting will be held to (1) assess ongoing Council activities; and, (2) discuss and plan future projects and programs. The agenda for the planned meeting is being developed and will be posted at *www.fitness.gov* when it has been finalized.

The meeting that is scheduled to be held on May 16, 2016, is open to the public. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276–9567 no later than close of business on May 2, 2016, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to *rsvp.fitness@hhs.gov* or by calling (240) 276–9567. Registration for public attendance must be completed before close of business on May 9, 2016.

Dated: March 11, 2016.

Tasha Bradley,

Director of Communications, Office of the President's Council on Fitness, Sports, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2016–06810 Filed 3–24–16; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a telephone conference call. This call will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to participate in the call should email *OMH-ACMH@hhs.gov* by April 12, 2016. Instructions regarding participating in the call and how to provide verbal public comments will be given at the time of preregistration.

Information about the meeting is available from the designated contact and will be posted on the Web site for the Office of Minority Health (OMH), *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH Web site under the heading *About OMH.*

DATES: The conference call will be held on April 14, 2016, 11:00 a.m.–1:00 p.m. ET

ADDRESSES: Instructions regarding participating in the call will be given at the time of preregistration.

FOR FURTHER INFORMATION CONTACT: Dr. Minh Wendt, Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240–453–8222; fax: 240–453–8223; email *OMH-ACMH@hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

Topics to be discussed during this conference call include planning for upcoming in-person meetings and finalizing the charge and the formation of the data workgroup.

This call will be limited to 125 participants. The OMH will make every effort to accommodate persons with special needs. Individuals who have special needs for which special accommodations may be required should contact Professional and Scientific Associates at (703) 234–1700 and reference this meeting. Requests for special accommodations should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email, mail, or fax their comments to the designated contact at least seven (7) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email *OMH-ACMH@hhs.gov* or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on April 8, 2016.

Dated: March 2, 2016.

Minh Wendt,

Designated Federal Officer, Office of Minority Health, U.S. Department of Health and Human Services.

[FR Doc. 2016–06809 Filed 3–24–16; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of 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 concerning the final effect of the HHS decision to designate a class of employees from the Battelle Laboratories-King Avenue in Columbus, Ohio, 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 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION: