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FDA is announcing the availability of a draft guidance for industry entitled “General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.”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 drug products is 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.

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

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

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.
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 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,

[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 46–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION: