

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 22, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for XTANDI (NDA 203-415) was initially submitted on May 22, 2012.

3. *The date the application was approved:* August 31, 2012. FDA has verified the applicant's claim that NDA 203-415 was approved on August 31, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 101 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-31824 Filed 12-17-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Intent To Establish the 2018 Physical Activity Guidelines Advisory Committee and Solicitation of Nominations for Appointment to the Committee Membership

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the intent to establish a Physical Activity Guidelines Advisory Committee (Committee). It is planned for the Committee to be established in calendar year 2016. This notice also serves to announce that an invitation is being extended for nominations of qualified candidates to be considered for appointment as a member of the Committee.

DATES: Nominations for membership on the Committee must be submitted by 6:00 p.m. ET on Friday, February 5, 2016.

ADDRESSES: Nominations should be submitted by email to PAGACnominations@hhs.gov. This address can be accessed online at the following address: www.health.gov/paguidelines. Nominations may also be sent to the following address: Richard D. Olson, M.D., M.P.H., Designated Program Official, 2018 Physical Activity Guidelines Advisory Committee; HHS/OASH/ODPHP; 1101 Wootton Parkway, Suite LL-100; Rockville, MD 20852; Telephone: (240) 453-8280.

FOR FURTHER INFORMATION CONTACT: Designated Program Official, 2018 Physical Activity Guidelines Advisory Committee, Richard D. Olson and/or Alternate Designated Program Official, Katrina L. Piercy, Ph.D., R.D., HHS/OASH/ODPHP; 1101 Wootton Parkway, Suite LL-100; Rockville, MD 20852; Telephone: (240) 453-8280. Additional information is available at www.health.gov/paguidelines.

SUPPLEMENTARY INFORMATION:

Purpose: The inaugural *Physical Activity Guidelines for Americans* (PAG), issued in 2008, represents the first major federal review of the benefits of physical activity. The PAG provides science-based advice on how physical activity can help promote health and reduce the risk of chronic disease. The PAG serves as the benchmark and primary, authoritative voice of the federal government for providing

science-based guidance on physical activity, fitness, and health in the United States. Five years after the first edition of the PAG was released, ODPHP, in collaboration with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the President's Council on Fitness, Sports, and Nutrition (PCFSN) led development of the *PAG Midcourse Report: Strategies to Increase Physical Activity Among Youth*. The 2nd edition of the *Physical Activity Guidelines* will build upon the 1st edition and provide a foundation for federal recommendations and education for physical activity programs for Americans, including those at risk for chronic disease.

The Committee will be established as a discretionary federal advisory committee and governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C., App.). The work of the Committee will be solely advisory in nature and time-limited. Formation of the Committee is necessary and in the public interest. The Committee will examine the current PAG, take into consideration new scientific evidence and current resource documents, and then develop a scientific advisory report to be submitted to the Secretary of HHS that outlines its science-based recommendations and rationale. The scientific report will be used by the federal government to develop the 2nd edition of the *Physical Activity Guidelines for Americans*. The Committee's duties do not include developing the policy, a draft of the policy, or determining how future policy might be implemented by the federal government. For those interested in reviewing the *Physical Activity Guidelines for Americans*, the 2008 Advisory Committee Scientific Report, or the PAG Midcourse Report, they are available at www.health.gov/paguidelines.

The Committee is expected to begin meeting in summer of 2016. The Committee is expected to meet approximately five times during the course of its operation. Pursuant to FACA, all meetings of the full Committee will be open to the public.

Individuals selected for appointment to the Committee will be invited to serve as members until the charter expires or the Committee accomplishes its mission. In keeping with FACA, the charter will expire two years from the date it is established. The Committee will operate until its report is delivered to the Secretary or the charter expires, whichever comes first. There will be no

stipend authorized to be paid to the members for performance of their official duties. However, Committee members will be authorized to receive per diem and reimbursement for travel expenses incurred for attending public meetings.

Structure: It is proposed that the Committee will consist of 11–17 members; one or two members will be selected to serve as the Chair, Vice Chair, and/or Co-Chairs. To be eligible for consideration of appointment to the Committee, individuals should be knowledgeable of current scientific research in human physical activity and be respected and published experts in their fields. They should be familiar with the purpose, communication, and application of federal physical activity guidelines and have demonstrated interest in the public's health and well-being through their research and/or educational endeavors. Expertise is sought in specific specialty areas related to physical activity and health promotion or disease prevention, including but not limited to: Health promotion and chronic disease prevention; bone, joint, and muscle health and performance; obesity and weight management; physical activity and risk of musculoskeletal injury; physical activity and cognition; physical activity within specific settings, such as preschool/childcare, schools (e.g., activity breaks, physical education), or the community/built environment; physical activity dose-response; sedentary behavior; behavior change; systematic reviews; and special populations including children, older adults, individuals with disabilities, or women who are pregnant.

Nominations: HHS will consider nominations, including self-nominations, for Committee membership of individuals qualified to carry out the above-mentioned tasks. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) The name, address, daytime telephone number, and email address of the nominator and the individual being nominated; (2) a letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee that the nominee is willing to serve as a member of the Committee; and (3) a current copy of the nominee's curriculum vitae (CV) no more than 10 pages in length. Inclusion of the following is requested in the CV: (1) Current and/or past grant awards; (2)

publications showing both breadth and experience in areas of specialization; (3) paid and non-paid board and advisory appointments; and (4) education and occupational history.

All nominations must include the required information. Incomplete nominations will not be processed for consideration. Federal employees should not be nominated for consideration of appointment to this Committee.

Equal opportunity practices regarding membership appointments to the Committee will be aligned with HHS policies. When possible, every effort will be made to ensure that the Committee is a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons with disabilities. Individuals will be appointed to serve as members of the Committee to represent balanced viewpoints of the scientific evidence, not to represent the viewpoints of any specific group.

Members of the Committee will be classified as special government employees (SGEs) during their term of appointment to the Committee, and as such are subject to the ethical standards of conduct for federal employees. Upon entering the position and annually throughout the term of appointment, members of the Committee will be required to complete and submit a report of their financial holdings, consultancies, and research grants and/or contracts. The purpose of this report is to determine if the individual has any interest and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee.

Dated: December 15, 2015.

Don Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2015–31837 Filed 12–17–15; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 for Nursing Research.

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 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: January 26–27, 2016.

Open: January 26, 2016, 1:00 p.m. to 4:45 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, Room 620/630, Bethesda, MD 20892.

Closed: January 27, 2016, 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, Room 620/630, Bethesda, MD 20892.

Contact Person: Ann R. Knebel, DNSC, RN, FAAN, Deputy Director, National Institute of Nursing Research, National Institutes of Health, 31 Center Drive, Building 31, Room 5B05, Bethesda, MD 20892, 301–496–8230, knebelar@mail.nih.gov.

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 instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors 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: www.nih.gov/ninr/aadvisory.html, 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)