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.

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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/daycare, 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.

**Closing:**


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