

sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 28, 2017.

Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that SPINRAZA (nusinersen), manufactured by Biogen Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:
Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4842, FAX: 301-796-9858, email: larry.bauer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that SPINRAZA (nusinersen), manufactured by Biogen Inc., meets the criteria for a priority review voucher. SPINRAZA (nusinersen) is indicated for the treatment of spinal muscular atrophy in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about SPINRAZA (nusinersen), go to the "Drugs@FDA" Web site at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: February 28, 2017.

Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the 2018 Physical Activity Guidelines Advisory Committee

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act (FACA), the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the third meeting of the 2018 Physical Activity Guidelines Advisory Committee (2018 PAGAC or Committee) will be held. This meeting will be open to the public via videocast.

DATES: The meeting will be held on March 23, 2017, from 8:00 a.m. E.T. to 5:30 p.m. E.T.

ADDRESSES: The meeting will be accessible by videocast on the Internet.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Officer, 2018 Physical Activity Guidelines Advisory Committee, Richard D. Olson, M.D., M.P.H. and/or Alternate Designated Federal Officer, Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite LL-100; Rockville, MD 20852; Telephone: (240) 453-8280. Additional information is available at www.health.gov/paguidelines.

SUPPLEMENTARY INFORMATION: The inaugural *Physical Activity Guidelines for Americans* (PAG), issued in 2008, represents the first comprehensive guidelines on physical activity issued by the federal government. 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 for Americans. Five years after the first edition 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 second edition of the PAG will build upon the first edition and provide a foundation for federal recommendations and education for physical activity programs for Americans, including those at risk for chronic disease.

Appointed Committee Members: The Secretary of HHS appointed 17 individuals to serve as members of the 2018 PAGAC in June 2016. Information on Committee membership is available at www.health.gov/paguidelines/second-edition/committee.

Committee's Task: The work of the 2018 PAGAC will be time-limited and solely advisory in nature. The Committee will develop recommendations based on the preponderance of current scientific and medical knowledge using a systematic review approach. The Committee will examine the current PAG, take into consideration new scientific evidence and current resource documents, and develop a scientific report to the Secretary of HHS that outlines its science-based advice and recommendations for development of the second edition of the PAG. The Committee will hold approximately five public meetings to review and discuss recommendations. The first meeting was held in July 2016 and the second in