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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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.

[FR Doc. 2017–04231 Filed 3–3–17; 8:45 am]

BILLING CODE 4164–01–P

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/DevelopingProductsforRareDiseasesConditions/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.

[FR Doc. 2017–04228 Filed 3–3–17; 8:45 am]

BILLING CODE 4164–01–P

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

October 2016. It is anticipated that future meetings will be held in the third weeks of July 2017 and October 2017. Meeting dates, times, locations, and other relevant information will be announced at least 15 days in advance of each meeting via **Federal Register** notice. As stipulated in the charter, the Committee will be terminated after delivery of its report to the Secretary of HHS or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA and to promote transparency of the process, deliberations of the Committee will occur in a public forum. At this meeting, the Committee will continue its deliberations from the last public meeting.

Meeting Agenda: The meeting will include review of subcommittee work since the last public meeting and deliberation by the full Committee, discussion of overarching issues, and plans for future Committee work.

Meeting Registration: The meeting is open to the public via videocast; pre-registration is required. To register, please visit *www.health.gov/paguidelines.* After registration, individuals will receive videocast access information via email. To request a special accommodation, please email *jennifer.gillissen@kauffmaninc.com.*

Public Comments and Meeting Documents: Written comments from the public will be accepted throughout the Committee's deliberative process and can be submitted and/or viewed at *www.health.gov/paguidelines/pcd/.* Documents pertaining to Committee deliberations, including meeting agendas and summaries will be available on *www.health.gov/paguidelines.* Meeting information, thereafter, will continue to be accessible online and upon request at the Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852; Telephone: (240) 453–8280; Fax: (240) 453–8281.

Dated: February 23, 2017.

Don Wright,

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

[FR Doc. 2017–04170 Filed 3–3–17; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0990–0278–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0278, which expires on August 31, 2017. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before May 5, 2017.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* and *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

Information Collection Request Title: Federal-wide Assurance Forms.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting Office of Management and Budget, OMB approval on a three year extension of the Federal-wide Assurance (FWA). The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103. The respondents are institutions engaged in human subject research that is conducted or supported by HHS.

Need and Proposed Use of the Information: OHRP is the HHS component charged with fulfilling the statutory mandates of these provisions of the PHS Act and enforcing HHS regulations at 45 CFR part 46. The FWA provides a simplified assurance process that replaced the prior assurance mechanisms used by OHRP, all of which were more complicated and burdensome than the FWA. The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the PHS Act and the requirements of HHS regulations at 45 CFR 46.103.

Likely Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, Federal, State, Local, or Tribal Governments.

The total annual burden hours estimated for this ICR are summarized in the table below.

ESTIMATED ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Federal-wide Assurance (FWA)	14,000	2.0	0.50	14,000

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2017–04249 Filed 3–3–17; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development