(b) How do you/your child weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include headache, nausea, fatigue, weight gain)

(c) How do you/your child weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are infections, organ damage or failure, suicidal thoughts)

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://autismpfdd.eventbrite.com*. Persons interested in attending this public meeting must register by April 24, 2017. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Shanon Woodward (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients and patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients and patient representatives also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 17, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient representatives who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm529043.htm*.

Dated February 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04229 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–2016–P–1725]

Determination That FLONASE (Fluticasone Propionate) Nasal Spray, 0.05 Milligram, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 milligram (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and this determination will allow FDA to continue to approve ANDAs for fluticasone propionate nasal spray, 0.05 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 301–796–8767.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, is the subject of NDA 020121, held by GlaxoSmithKline, and initially approved on October 19, 1994. FLONASE is indicated for the management of the nasal symptoms of perennial nonallergic rhinitis in adult and pediatric patients aged 4 years and older.

In a letter dated May 25, 2016, GlaxoSmithKline notified FDA that prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 20, 2016 (Docket No. FDA–2016–P–1725), under 21 CFR 10.30, requesting that the Agency determine whether prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, from

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