III. Meeting Attendance and Participation

If you wish to attend this meeting, visit https://autismpfd.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 Shannon 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.


Leslie Kux, Associate Commissioner for Policy.
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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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.


Leslie Kux,
Associate Commissioner for Policy.

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

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. 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/.


Leslie Kux,
Associate Commissioner for Policy.

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

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.