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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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

Issue of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing 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/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/.


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.