the liver, and glomerular filtration and tubular secretion of unchanged drug by the kidneys (*i.e.,* renal excretion). If a drug is eliminated primarily through renal excretion, then impaired renal function usually alters the drug's PK to an extent that the dosage regimen may need to be changed from that used in patients with normal renal function. For most drugs that are likely to be administered to patients with impaired renal function, it is important to characterize PK in subjects with impaired renal function to provide appropriate dosing recommendations.

The safety and efficacy of a drug are generally established for a particular dosage regimen (or range of dosage regimens) in late-phase clinical trials that enroll patients from the target patient population. Frequently, however, individuals with advanced kidney disease are explicitly excluded from participation in these studies, hindering the assessment of the effects of severely impaired kidney function on the PK of a drug or the patient's clinical response. A well-planned drug development program can enable prospective dosage adjustment based on the observed or expected changes in the PK of a drug due to impaired renal function prior to initiating phase 2 or phase 3 trials.

This guidance replaces the 2010 version and provides updated recommendations on the following topics:

(1) When a dedicated study of a drug's PK in subjects with impaired renal function is recommended and when it may not be needed;

(2) The design and conduct of pharmacokinetic studies in subjects with impaired renal function;

(3) Considerations for characterizing a drug's PK in patients undergoing intermittent or continuous dialytic therapies;

(4) The use of pharmacokinetic information from phase 2 and 3 studies to inform dosing recommendations for patients with renal impairment; and

(5) The analysis and reporting of the results of studies that characterize the impact of renal impairment and how these data inform dosing.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collection of information in 21 CFR 201.57 has been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: August 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19597 Filed 9–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, Health and Human Services (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 (the 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 approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that VILTEPSO (viltolarsen) manufactured by Nippon Shinyaku Co., Ltd. (NS Pharma Inc., U.S. Agent), meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved 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 approved rare pediatric disease product applications that meet certain criteria. FDA has determined that VILTEPSO (viltolarsen) manufactured by Nippon Shinyaku Co., Ltd. (NS Pharma Inc., U.S. Agent), meets the criteria for a priority review voucher.

VILTEPSO (viltolarsen) is indicated for the treatment of Duchenne Muscular Dystrophy in patients amenable to Exon 53 Skipping.

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 *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* **FOR FURTHER INFORMATION** about VILTEPSO (viltolarsen) go to the ''*Drugs@FDA*'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: August 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19604 Filed 9–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the Advisory Committee on Organ Transplantation (ACOT) has been renewed. The effective date of the renewed charter is August 31, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Designated Federal Officer, HRSA Division of

Transplantation, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W60, Rockville, Maryland 20857; 301–443–6839; or *rwalsh@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The ACOT provides advice and recommendations to the Secretary of HHS (Secretary) on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines. ACOT is authorized by 42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended; 42 CFR 121.12.

The Committee is governed by provisions of the FACA, Public Law 92–463 (5 U.S.C. App. 2), which sets forth standards for the formation of advisory committees. The recommendations of the ACOT inform HHS programs and activities to support organ donation and transplantation. ACOT's recent recommendations in support of expanding reimbursement of living organ donor expenses were cited as a key part of the rationale for recent proposed HHS actions to expand this activity consistent with the President's Executive Order on Advancing American Kidney Health. The charter renewal for the ACOT was approved on August 31, 2020, which will also stand as the filing date. Renewal of the ACOT charter gives authorization for the committee to operate until August 31, 2022.

A copy of the ACOT charter is available on the ACOT website at *https://www.organdonor.gov/about-dot/acot.html*. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/*.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–19644 Filed 9–3–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for advisory committee member nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS (Secretary). HRSA is seeking nominations of qualified candidates for appointment to five positions on the Committee for terms of up to 4 years.

DATES: Written nominations for membership on the Committee must be received on or before September 22, 2020.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Mia Morrison, MPH at *ACHDNC@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: Mia Morrison, MPH, Maternal and Child Health Bureau, HRSA 5600 Fishers Lane, Room 18W–68, Rockville, MD 20857; 301–443–2521; or *ACHDNC@hrsa.gov.* A copy of the Committee charter and list of the current membership may be obtained by accessing the Committee website at *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/about/members.pdf.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders.

In addition, the Committee provides advice and recommendations to the Secretary concerning grants, projects and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns, and children having or at risk for heritable disorders. The Committee meets four times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the ACHDNC Chair. The Committee is governed by the provisions of Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees, and its Charter.

The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by HRSA pursuant to section 2713 of the PHS Act, codified at 42 U.S.C. 300gg–13. Under this provision, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations

HRSA is requesting nominations for voting members to serve on the Committee to fill up to five positions for terms of up-to 4 years. The Secretary appoints Committee members with the expertise needed to fulfill the duties of the Advisory Committee. Nominees sought are medical, technical, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children with, or at risk for having, heritable disorders; individuals who have expertise in ethics (*e.g.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having demonstrated expertise about or concern with heritable disorders; and/or representatives from such federal agencies, public health constituencies, and medical professional societies with such expertise. Interested applicants may self-nominate or be nominated by another individual or organization. Nominees must reside in the United States and cannot be funded for international travel expenses.

Individuals selected for appointment to the Committee will be invited to serve for up-to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for