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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and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