Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–23291 Filed 10–24–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE19–001; Correction

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE19–001; October 30–November 2, 2018, 8:30 a.m.–5:00 p.m., EDT which was published in the **Federal Register** on August 23, 2018 Volume 83, Number 164, pages 42655–42656.

The date should read as follows: October 29, 2018, 3:00 p.m.–5:00 p.m., EDT, October 30–November 2, 2018, 8:00 a.m.–5:00 p.m., EDT.

FOR FURTHER INFORMATION CONTACT: Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, (404)639–0913; *mwalters@cdc.gov*.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–23297 Filed 10–24–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

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 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 REVCOVI (elapegademase-lvlr) Injection, manufactured by Leadiant Bioscience Inc., 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 REVCOVI (elapegademase-lvlr) Injection, manufactured by Leadiant Bioscience Inc., meets the criteria for a priority review voucher. REVCOVI (elapegademase-lvlr) Injection is indicated for the treatment of Adenosine Deaminase-Severe Combined Immunodeficiency (ADA–SCID) 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 *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about REVCOVI (elapegademase-lvlr) Injection, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23308 Filed 10–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3462]

Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.'' The draft guidance addresses the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, this draft guidance covers the statutory verification system requirements that include quarantine and investigation of a product determined to be suspect and quarantine and disposition of a product determined to be illegitimate. The draft guidance also addresses the statutory requirement for notification to the Agency of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser after a suspect product investigation because it is determined that the product is not an illegitimate product.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or