services to most efficiently and effectively serve the needs of low-income children and their families. ACF aims to understand strategies used to support partnerships, including the federal barriers to agency collaboration. In support of achieving these goals, the study team is conducting ''virtual site visits'' with six programs that offer coordinated services. The study team will gather information through interviews with program staff members, such as agency leaders or frontline staff, and focus groups with parents.

Data collection activities will include up to six program ''virtual site visits.'' ''Virtual site visits'' include semi-structured interviews with up to 30 total staff at each site and focus groups with 8–10 parents at each site. Semi-structured interviews with program and partner staff will obtain in-depth information about the goals and objectives of programs, the services provided, how the coordinated services are implemented, how staffing is managed, data use, and any facilitators and barriers to coordination. Focus groups with parents participating in the program will provide the opportunity to learn about how parents perceive the program; how it meets their needs; what benefits they gain from the program; and how they enroll, participate, and progress through the program.

Respondents: Lead program and partner program staff members working in six programs across the United States that coordinate early care and education services with family economic security services and/or other health and human services, as well as parents receiving services from these programs. Staff respondents will be selected with the goal of having staff represent each level of the organization. Parents who have participated in the program for at least 6 months and who receive early childhood services and at least one other program service will be invited to participate in focus groups.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Master Virtual Site Visit Interview Protocol	180	1	2	360
Parent Virtual Focus Group Protocol	60	1	1	60

Estimated Total Annual Burden Hours: 420.

Authority: 42 U.S.C. 9858(a)(5).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–20266 Filed 9–14–20; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1153]

Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of September 2, 2020. The document announced the availability of post-marketing pediatric-focused safety reviews of products posted between September 23, 2019, and September 1, 2020, on FDA's website but not presented at the September 15, 2020, Pediatric Advisory Committee meeting. The document was published with the incorrect product name for one of the post-marketing pediatric-focused safety reviews listed under Center for Biologics Evaluation and Research. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 2, 2020 (85 FR 54580), appearing on page 54580 in FR Doc. 2020–19835, the following correction is made:

On page 54581, in the first column, under Center for Biologics Evaluation and Research, ''9. QPAN H5N1 Vaccine (Influenza A (H5N1) virus monovalent vaccine, adjuvanted)'' is corrected to read ''9. Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted.''

Dated: September 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20329 Filed 9–14–20; 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 (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 TRIKAFTA (elexacaftor/tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, 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 TRIKAFTA (elexacaftor/tezacaftor/ivacaftor),

manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher.

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) is indicated for the treatment of patients with cystic fibrosis aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator gene.

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 TRIKAFTA (elexacaftor/tezacaftor/ivacaftor), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/*.

Dated: September 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20320 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2936]

Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' This guidance identifies the principles FDA uses for recognizing a standard, and it explains the extent of recognition and other supplementary information. It provides information on how you may request recognition as well as circumstances under which FDA may withdraw recognition. This guidance also responds to a provision of the 21st Century Cures Act (Cures Act) by updating published guidance on these topics.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2936 for ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and