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),