4164-01-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: 9/14/2020 8:45 am; Publication Date: 9/15/2020]