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 FILSUVEZ (birch triterpenes), manufactured by Amryt Pharmaceuticals, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that FILSUVEZ (birch triterpenes), manufactured by Amryt Pharmaceuticals, meets the criteria for a priority review voucher. FILSUVEZ (birch triterpenes) gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

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 *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about FILSUVEZ (birch triterpenes), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00400 Filed 1–10–24; 8:45 am]

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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, 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) 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 ADZYNMA (ADAMTS13, recombinant-krhn), manufactured by Takeda Pharmaceuticals U.S.A., Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ADZYNMA (ADAMTS13, recombinant-krhn), manufactured by Takeda Pharmaceuticals U.S.A., Inc., meets the criteria for a priority review voucher.

ADZYNMA (ADAMTS13, recombinant-krhn) is indicated for prophylactic or on-demand enzyme replacement therapy in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about ADZYNMA (ADAMTS13, recombinant-krhn), go to the Center for Biologics Evaluation and Research's Approved Blood Products website at *https://www.fda.gov/vaccines-blood-biologics/adzynma.*

Dated: January 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00401 Filed 1–10–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2512]

Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin; International Council for Harmonisation; 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 final guidance for industry entitled ''Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance is intended to describe risk-based principles and mitigation strategies to assure the viral safety of biotechnology products, including the data necessary to submit in a marketing application. The guidance also finalizes the updates based on advances in scientific knowledge and regulatory expectations to the first version of the ICH guidance for industry ''Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin,'' issued in September 1998. Lastly, the guidance replaces the draft guidance ''Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin'' issued on November 14, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 11, 2024.

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