During the assessment of an ANDA, FDA considers important issues that are central to product evaluation. Sometimes, an applicant may disagree with FDA, and because these disagreements often involve intricate matters, it is critical to have procedures in place to ensure open and prompt consideration of an applicant's concern(s). The procedures and policies described in this guidance are intended to formalize FDA's current and historical practices and to continue to promote rapid and fair resolution of eligible requests between an applicant and FDA. This draft guidance revises the draft guidance of the same title issued on October 12, 2017 (82 FR 47531). This revision is being issued to reflect the most recent reauthorization of GDUFA in the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Division F, Title III, Pub. L. 117–180, 136 Stat. 2155), and to clarify what matters are appropriate for requests for reconsideration.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Requests for Reconsideration at the Division Level Under GDUFA.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for FDA Approval To Market a New Drug

OMB Control Number 0910–0001—Revision

The information collection request supports the Agency's draft guidance entitled, ''Requests for Reconsideration at the Division Level Under GDUFA.'' As discussed in section I of this notice, this draft guidance provides information to respondents regarding procedures for submitting requests for reconsideration, including details on the content and format of the submission. Respondents to the collection of information are applicants of ANDAs. Based on available data with regard to similar information collections, FDA's Center for Drug Evaluation and Research will receive approximately 310 requests for reconsideration annually from 155 respondents. Because we estimate it will take 5 hours to prepare a request for reconsideration, we estimate it will take an average of 1,550 total hours annually for respondents to prepare and submit requests for reconsideration.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section IV: Procedures for Submitting and Responding to a Request for Reconsideration	155	2	310	5	1,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance refers to previously approved FDA collections of information found in FDA regulations. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information pertaining to the GDUFA III commitment letter, meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00403 Filed 1–10–24; 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, 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 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]

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, 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]

BILLING CODE 4164–01–P

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