II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in FDA's guidance entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs'' have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21689 Filed 10–5–21; 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; Withdrawal

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

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the notice that published in the **Federal Register** of September 30, 2021, that announced the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The **Federal Register** notice was published in error and is being withdrawn.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, 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: In the **Federal Register** of September 30, 2021 (86 FR 54219) in FR Doc. 2021–21311, FDA announced the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application for RETHYMIC (allogeneic processed thymus tissue-agdc), manufactured by Enzyvant Therapeutics, GmbH. The **Federal Register** notice was published in error and is being withdrawn.

Dated: October 1, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21823 Filed 10–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1402]

Biomarkers and Surrogate Endpoints in Clinical Studies To Support Effectiveness of New Animal Drugs; Guidance for Industry; Availability

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

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #267 entitled ''Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs.'' The guidance describes FDA's current thinking with respect to incorporating biomarkers and surrogate endpoints into proposed clinical investigational protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on October 6, 2021.

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–2020–D–1402 for ''Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs.'' 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, 240–402–7500.

- 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