

ATEBRIOZ (zilurgisertib) tablets for oral use is indicated to reduce the volume of total new heterotopic ossification (HO) in adults and pediatric patients aged 12 years and older with fibrodysplasia ossificans progressiva (FOP).

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/ForIndustry/DevelopingProductsforRareDiseaseConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ATEBRIOZ (zilurgisertib), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21910 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12279]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; EMCITATE (Tiratricol)

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 EMCITATE (tiratricol), approved September 28, 2026, manufactured by Rare Thyroid Therapeutics International AB meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Scott Winiecki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993–0002, 301–771–1519 Scott.Winiecki@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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined EMCITATE (tiratricol), manufactured by Rare Thyroid Therapeutics International AB meets the criteria for a priority review voucher. EMCITATE (tiratricol) tablet is indicated for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome).

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/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about EMCITATE (tiratricol) go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21911 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–11188]

Electronic Submission Template for Investigational Device Exemption (IDE) Applications; Draft Guidance for Sponsors and Food and Drug Administration Staff; 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 the draft guidance titled “Electronic Submission Template for Investigational Device Exemption (IDE) Applications.” FDA is issuing this draft guidance for sponsors submitting IDE applications to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those sponsors to the current publicly available resources and associated content developed to support IDE electronic submissions to FDA. This draft guidance, when finalized, is intended to represent one of several

steps in meeting FDA’s commitment to the development of electronic submission templates to serve as guided submission preparation tools for sponsors to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 28, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2026–D–11188 for “Electronic