

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.

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## 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](mailto: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.

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## 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

Submission Template for Investigational Device Exemption (IDE) Applications.” 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 contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document titled “Electronic Submission Template for Investigational Device

Exemption (IDE) Applications” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is issuing this draft guidance document to introduce sponsors submitting IDE applications to CDRH and CBER to the current resources and associated content developed and made publicly available to support the electronic submissions of Original IDE applications, IDE supplemental applications, and amendments to Original IDE and IDE supplemental applications, and related IDE submissions to FDA. This draft guidance 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. When finalized, this guidance will also facilitate the implementation of the FDA’s mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

FDA’s final guidance document published on July 15, 2020 (85 FR 42864): “Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act” (hereafter referred to as the “745A(b) device parent guidance”) provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with

individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. When finalized, this guidance will provide such information for IDE electronic submissions solely in electronic format.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this draft guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.*, standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as *must* or *required*, this document is not subject to the usual restrictions in FDA’s good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see § 10.115(d)). To the extent that this draft guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued consistent with FDA’s good guidance practices regulation (§ 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on Electronic Submission Template for IDE Applications. With the exception of the guidance’s provision of requirements for “standards,” “timetable,” or “criteria for waivers” and “exemptions” pursuant to section 745A(b) of the Federal Food, Drug, and Cosmetic Act, 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

##### **II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>.

[www.fda.gov/regulatory-information/search-fda-guidance-documents](http://www.fda.gov/regulatory-information/search-fda-guidance-documents), or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Investigational Device Exemption (IDE) Applications” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007080 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

| 21 CFR part | Topic                                                                                    | OMB control No. |
|-------------|------------------------------------------------------------------------------------------|-----------------|
| 812 ...     | Investigational Device Exemption.                                                        | 0910–0078       |
| 820 ...     | Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR). | 0910–0073       |

Grace R. Graham,  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.  
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2742]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 27, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Color Additive Certification

OMB Control Number 0910–0216—Extension

This information collection supports FDA regulations governing certification for color additives used in foods, drugs, cosmetics, and medical devices. All color additives must have FDA-approval for their intended use and be listed in the color additive regulations before they are permitted for use in food, drugs, cosmetics, and many medical devices. Some color additives have an additional requirement: they are permitted only if they are from batches that FDA has certified under section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)). This means that FDA chemists have analyzed a sample from the batch and have found that it meets the requirements for composition and purity stated in the regulation, called a “listing regulation,” for that color additive. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are established in 21 CFR part 80. Procedures for color additive certification are set forth in part 80, subpart B (§§ 80.21 through 80.39) and communicate required data elements for requests for certification, limitations of certificates, exemptions from certification for color additive mixtures, treatment of batches pending and after certification, and recordkeeping requirements for respondents to whom a certificate is issued. During the batch certification procedure, a manufacturer of color additives must submit a “request for certification” that provides information about the batch, accompanied by a representative sample of a new batch of color additive, to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate that contains a certification lot number for the batch. The batch can then be used in FDA-regulated products marketed in the United States, in compliance with the uses and restrictions in that color additive’s listing regulation. If the sample does not meet the requirements, the batch will be rejected. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

FDA’s web-based color certification information system is available for respondents to request color certification online, track their submissions, and obtain account status information. Prior to submitting a request for certification, the manufacturer must open a color certification account by sending a letter, as an email attachment, signed by responsible company representative, to FDA’s Office of Cosmetics and Colors at [color.cert@fda.hhs.gov](mailto:color.cert@fda.hhs.gov). System certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates.

We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification. The user fees support FDA’s color certification program. Additional information about color additive certification is available at: <https://www.fda.gov/industry/color-additives/color-certification>.

The purpose for collecting this information is to help the Agency assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States.