

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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993, 301-796-6169; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a final guidance for industry titled “Postapproval Pregnancy Safety Studies.” The purpose of this guidance is to provide sponsors and investigators with recommendations on how to design investigations to assess the safety outcomes in pregnant women exposed to drug and biological products regulated by FDA, in the postapproval setting. Currently, collection of safety data in drug and biological products used during pregnancy usually occurs after approval. Pregnancy registries have been used to collect these data. However, in the years since FDA first issued guidance on this topic, scientific methodologies for assessing the safety of drug and biological products used during pregnancy in the postmarketing setting have evolved.

This guidance finalizes the draft guidance titled “Postapproval Pregnancy Safety Studies” issued on May 9, 2019 (84 FR 20371). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the following: (1) clarifying the section on pregnancy registries, including the addition of a subsection on statistical methods; (2) broadening the scope of the complementary study methods sections; (3) expanding the discussion on data

collection in situations when rare exposure to a drug during pregnancy is anticipated; and (4) updating terminology to include descriptive pregnancy safety studies. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Postapproval Pregnancy Safety Studies.” 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. FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be an E.O. 14192 deregulatory action.

##### **II. Paperwork Reduction Act of 1995**

While this guidance contains no 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 21 CFR 314.50(d), 314.80(c)(2)(iii), and 314.81(b)(2)(vii) pertaining to submissions of new drug applications for submitting postmarketing safety reports, postmarketing study updates in annual reports, and formal meetings between sponsors or applicants and FDA have been approved under OMB control number 0910-0001. The collections of information in 21 CFR 312.23(a)(6) pertaining to submitting pregnancy registry design considerations in a protocol for investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practices have been approved under OMB control number 0910-0139. The collections of information in 21 CFR parts 310.305(c) and 314.80(c)(2)(iii) and (e) for submitting postmarketing safety reports have been approved under OMB control number 0910-0230. The collections of information in 21 CFR parts 310, 314, 600, and 803 for submitting postmarketing safety reports under MedWatch have been approved under OMB control number 0910-0291. The collections of information in 21 CFR 601 pertaining to biologics license applications have been approved under OMB control number 0910-0338. The

collections of information in 21 CFR 201.56 and 201.57 pertaining to human prescription drug labeling have been approved under OMB control number 0910-0572.

##### **III. Electronic Access**

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

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026-09268 Filed 5-8-26; 8:45 am]

**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2013-D-1319]

##### **Pulmonary Tuberculosis: Developing Drugs for Treatment; 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 titled “Pulmonary Tuberculosis: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of new antibacterial drugs for the treatment of pulmonary tuberculosis (TB). This guidance finalizes the draft guidance of the same title issued on December 15, 2022.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 11, 2026.

**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](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-2013-D-1319 for "Pulmonary Tuberculosis: Developing Drugs for Treatment." 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 6150, Silver Spring, MD 20993, 240-402-5328.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a final guidance for industry titled "Pulmonary Tuberculosis: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of investigational drugs for the treatment of pulmonary TB.

This guidance finalizes the draft guidance of the same name issued on December 15, 2022 (87 FR 76629). Specifically, this guidance addresses the FDA's current thinking regarding the overall development program for a new

investigational drug or drugs to be used in combination with drugs already approved for treatment of pulmonary TB or for other indications or as a new treatment regimen that includes one or more investigational drugs to support an indication for the treatment of pulmonary TB.

FDA's final guidance included edits and updated information after considering several public comments received on the draft guidance. Clarifying edits and updated information were included in the following areas of the guidance: nonclinical and safety considerations, study populations, efficacy endpoints, and trial design considerations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on "Pulmonary Tuberculosis: Developing Drugs for Treatment." 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

While this guidance contains no 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 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910-0119. The collections of information in 21 CFR part 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications have been approved under OMB control number 0910-0338.

##### III. Electronic Access

Persons with access to the internet may obtain the 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>.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026-09269 Filed 5-8-26; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2026-N-4573]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product; AVLAYAH (tvidenofusp alfa-eknm)

**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 AVLAYAH (tvidenofusp alfa-eknm), approved March 24, 2026, manufactured by Denali Therapeutics Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:**

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993-0002, 301-796-2771, [Quyen.Tran1@fda.hhs.gov](mailto:Quyen.Tran1@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 AVLAYAH (tvidenofusp alfa-eknm), manufactured by Denali Therapeutics Inc., meets the criteria for a priority review voucher. AVLAYAH (tvidenofusp alfa-eknm) injection is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients

weighing at least 5 kg prior to advanced neurologic impairment.

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 AVLAYAH (tvidenofusp alfa-eknm), 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. 2026-09242 Filed 5-8-26; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-N-2220]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications On Medical Devices and Radiation-Emitting Products

**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 June 10, 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 0910-0678. 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.

#### Testing Communications On Medical Devices and Radiation-Emitting Products

*OMB Control Number 0910-0678—Extension*

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications by FDA’s Center for Devices and Radiological Health (CDRH) involves many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about product use. Knowledge of consumer, caregiver, and healthcare professional decision-making processes will provide a better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels.

Second, as initial testing, the collected information will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, the collected information will allow FDA to ascertain the effectiveness of the messages and the distribution method in achieving the objectives of the message campaign. Evaluation of message campaigns is a vital link in continuous improvement of communications at FDA.

FDA expects to conduct studies under this generic information collection using a variety of research methods. We