

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