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 (tividenofusp 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 (tividenofusp 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.*

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 (tividenofusp alfa-eknm), manufactured by Denali Therapeutics Inc., meets the criteria for a priority review voucher. AVLAYAH (tividenofusp 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 (tividenofusp 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]

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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.*

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

estimate that the burden to respondents will average 16 minutes each (varying from 5 minutes to 90 minutes). FDA estimates the burden of this collection of information based on prior experience with the various types of data collection methods described earlier.

In the **Federal Register** of August 7, 2025 (90 FR 38155), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interviews	420	1	420	0.75 (45 minutes) ..	315
General Public Focus Group Interviews	288	1	288	1.50	432
Intercept Interviews: Central Location	200	1	200	0.25 (15 minutes ...	50
Intercept Interviews: Telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes) ..	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes) ..	200
Omnibus Surveys	1,200	1	1,200	0.17 (10 minutes) ..	204
Total (General Public)	8,908				2,121
Healthcare Professional Individual In-Depth Interviews	72	1	72	0.75 (45 minutes) ..	54
Healthcare Professional Focus Group Interviews	144	1	144	1.50	216
Total (Healthcare Professionals)	216				270
Total (Overall)	9,124				2,391

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09244 Filed 5–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: 0990–New–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the National Coordinator for Health IT, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the National Coordinator for Health IT (ONC), Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 10, 2026.

ADDRESSES: When commenting, please reference the document identifier 0990–New–60D and title of collection ''Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities''. Submit your comments to Talisha Searcy at *Talisha.searcy@hhs.gov* or by mail to: Talisha Searcy, ONC, Office of Policy, 330 C St. SW, Floor 7, STE 7028A, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting copies of supporting material, please include the document identifier 0990–New–60D and project title for reference to Talisha Searcy, *talisha.searcy@hhs.gov,* or call (240) 276–0642.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities.

Type of Collection: New Collection.

Abstract: The Office of the National Coordinator for Health Information Technology (ONC) is seeking a three-year generic approval to collect routine customer feedback on agency service delivery related to TEFCA. ONC oversees a TEFCA Recognized Coordinating Entity® (RCE®) to administer aspects of TEFCA. The RCE is responsible for developing, implementing, and maintaining the Common Agreement that establishes the baseline technical and legal requirements for health information networks to share electronic health information. The data collections under this clearance will be designed to standardize monitoring and performance reports for TEFCA participants. With the number of TEFCA participants on the rise, ONC is seeking approval to collect this information from TEFCA users to enhance the efficiency of program management.

Need and Proposed Use of the Information: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions and is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into TEFCA users and