

section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20764 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10786]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ZANVASTRO (zilganersen)

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 ZANVASTRO (zilganersen), approved September 3, 2026, manufactured by Ionis Pharmaceuticals, 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., Silver Spring, MD 20993–0002, 301–796–2771.

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 ZANVASTRO (zilganersen), manufactured by Ionis Pharmaceuticals, Inc., meets the criteria for a priority review voucher. ZANVASTRO (zilganersen) injection is indicated for the treatment of Alexander disease in pediatric and adult patients.

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 ZANVASTRO (zilganersen), 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. 2026–20769 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Submission to OMB for Review and Approval; Public Comment Request; Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 9, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to 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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title:

Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form, OMB No. 0906–XXXX—New.

Abstract: HRSA is proposing a new form to collect organizational National Provider Identifiers (Type 2 NPIs) and Centers for Medicare & Medicaid Services (CMS) Certification Numbers (CCNs) from organizations that apply for HRSA award funding through Grants.gov. The form will be completed as part of the Grants.gov funding application. This collection is limited to organizational identifiers and will only collect an NPI and/or CCN only from organizations that already have one. An organization is not required to have, or to obtain, an NPI or CCN in order to apply for or receive HRSA funding, and individual applicants (persons) are not asked to provide an individual (Type 1) NPI. Organizational NPIs are issued by the CMS through the National Plan and Provider Enumeration System. CCNs are issued by CMS to providers and suppliers that obtain Medicare or Medicaid certification.

The purpose of this proposed collection is to strengthen the evidence HRSA uses to understand how it meets its mission of improving health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs. This collection is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241), which authorizes the Secretary of HHS to conduct and support research, investigations, experiments, demonstrations, and studies relating to the causes; diagnosis; treatment; control; and prevention of disease, and to collect and make available information on those activities, including the provision of technical assistance on statistical methods.