

new drug application (NDA) for MONOFERRIC (NDA 208171) was initially submitted on 3/21/2019.

3. *The date the application was approved:* 1/16/2020. FDA has verified the applicant's claim that NDA 208171 was approved on 1/16/2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,136 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20766 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4567]

Determination That LASIX (Furosemide) Oral Solution, 10 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that LASIX (furosemide) oral solution, 10 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, Awo.Archampong-Gray@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or

suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LASIX (furosemide) oral solution, 10 mg/mL, is the subject of NDA 017688, held by Sanofi-Aventis U.S. LLC., and initially approved on March 8, 1977. LASIX is indicated in adults, infants, and children for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Oral LASIX may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents.

LASIX (furosemide) oral solution, 10 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated April 23, 2026 (Docket No. FDA–2026–P–4567), under 21 CFR 10.30, requesting that the Agency determine whether LASIX (furosemide) oral solution, 10 mg/mL, has been voluntarily withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LASIX (furosemide) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LASIX (furosemide) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LASIX (furosemide) oral solution, 10 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LASIX (furosemide) oral solution, 10 mg/mL, in the “Discontinued Drug Product List”

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.