

information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than October 15, 2026.

A. Federal Reserve Bank of Minneapolis (Mark Nagle, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *Michael Johnson, Litchfield, Minnesota*, to acquire voting shares of Darwin Bancshares, Inc. ("Company"), and thereby indirectly acquire voting shares of Perennial Bank ("Bank"), both of Darwin, Minnesota.

In addition, *Jeb Johnson, New London, Minnesota; Max Johnson, Bryce Johnson, and Josh Johnson, all of Darwin, Minnesota; Zachary Johnson, Grove City, Minnesota; Chad Johnson, Monticello, Minnesota; Rachael Larson, St. Cloud, Minnesota; and Krysta Roemeling, Avon, Minnesota*; to join the Johnson Family Control Group, a group acting in concert, to retain voting shares of Company, and thereby indirectly retain voting shares of Bank.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-P-4574]

Determination That ISTURISA (Osilodrostat) Tablets, 10 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA, Agency, or we) has determined that ISTURISA (osilodrostat) tablets, 10 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to

approve abbreviated new drug applications (ANDAs) for osilodrostat tablets, 10 mg if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993-0002, 301-796-3600, heather.dorsey@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.

ISTURISA (osilodrostat) tablets, 10 mg, is the subject of NDA 212801, held by Recordati Rare Diseases, Inc., and initially approved on March 6, 2020. ISTURISA is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative.

ISTURISA (osilodrostat) tablets, 10 mg, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Annora Pharma Private Limited submitted a citizen petition dated April 24, 2026 (Docket No. FDA-2026-P-4574), under 21 CFR 10.30, requesting that the Agency determine whether ISTURISA (osilodrostat) tablets, 10 mg, was withdrawn from sale 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 ISTURISA (osilodrostat) tablets, 10 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ISTURISA (osilodrostat) tablets, 10 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ISTURISA (osilodrostat) tablets, 10 mg, 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 ISTURISA (osilodrostat) tablets, 10 mg, 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. ANDAs that refer to ISTURISA (osilodrostat) tablets, 10 mg, may 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.

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