

**FOR FURTHER INFORMATION CONTACT:**  
Please send questions by email to Bridget Zachary by email [bridget.zachary@restorethegulf.gov](mailto:bridget.zachary@restorethegulf.gov) or call (504) 232-3750.

**SUPPLEMENTARY INFORMATION:** Section 1321(t)(2)(E)(ii)(III) of the *Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies Act of 2012* (33 U.S.C. 1321(t) and note) (RESTORE Act) and the Department of the Treasury's implementing regulation at 31 CFR 34.401(b) set forth certain notice and publication requirements. They require that for purposes of awards made under the Comprehensive Plan Component of the RESTORE Act, a State or Federal award recipient may make a subaward to or enter into a cooperative agreement with a nongovernmental entity that equals or exceeds 10 percent of the total amount of the award only if at least 30 days before the State or Federal award recipient enters into such an agreement, the Council publishes in the **Federal Register** and delivers to specified Congressional committees the name of the recipient and subrecipient; a brief description of the activity, including its purpose; and the amount of the award. This notice fulfills the **Federal Register** publication requirement.

#### Description of Proposed Action

As specified in the Council's 2021 Funded Priorities List, which is available on the Council's website at <https://www.restorethegulf.gov/our-work/fpl/fpl-3/>, RESTORE Act funds in the amount of \$24,300,000 will support the Texas Land Acquisition Program for Coastal Conservation Award to the Texas Commission on Environmental Quality. Under the Texas Land Acquisition Program for Coastal Conservation Award, Texas Commission on Environmental Quality will provide a subaward increase in the amount of \$1,500,000 to Armand Bayou Nature Center, a non-government organization, to acquire and preserve approximately 106 acres of habitat along Armand Bayou. This amount is added to the previous subaward of \$3,000,000 used for the purchase of 1,160 acres.

**Keala J. Hughes,**  
Director of External Affairs & Tribal Relations,  
Gulf Coast Ecosystem Restoration Council.

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#### GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 111132025-1111-03]

#### Senior Executive Service Performance Review Board Membership

**AGENCY:** Gulf Coast Ecosystem Restoration Council (GCERC).

**ACTION:** Notice of Performance Review Board (PRB) appointments.

**SUMMARY:** This notice announces the members of the Senior Executive Service (SES) Performance Review Board. The PRB is comprised of a chairperson and a mix of state representatives and career senior executives that meet annually to review and evaluate performance appraisal documents and provide a written recommendation to the Chairperson of the Council for final approval of each executive's performance rating, performance-based pay adjustment, and performance award.

**DATES:** The board membership is applicable beginning on 5/01/2025 and ending on 12/31/25.

**FOR FURTHER INFORMATION CONTACT:**  
Mary S. Walker, Executive Director, Gulf Coast Ecosystem Restoration Council, telephone 504-210-9982.

**SUPPLEMENTARY INFORMATION:** In accordance with 5 U.S.C. 4314(c)(4), the persons named below have been selected to serve on the PRB:

#### Gulf Coast Ecosystem Restoration Council

Walker, Mary S., Executive Director, [Mary.Walker@restorethegulf.gov](mailto:Mary.Walker@restorethegulf.gov), 504-210-9982

#### Department of Interior

Blanchard, Mary Josie, Deputy Director, Environmental Protection Compliance, [MaryJosie\\_Blanchard@ios.doi.gov](mailto:MaryJosie_Blanchard@ios.doi.gov), 202-208-3406

#### State of Florida

Blalock, Adam, Deputy Secretary for Ecosystem Restoration, [Adam.Blalock@floridadep.gov](mailto:Adam.Blalock@floridadep.gov), 850-245-2118

#### State of Texas

Schar, Steven, Deputy Executive Director, Texas Commission on Environmental Quality, [steven.schar@tceq.texas.gov](mailto:steven.schar@tceq.texas.gov), 512-239-3900

#### Environmental Protection Agency

Fotouhi, David, Deputy Administrator, EPA, [Atkinson.Emily@epa.gov](mailto:Atkinson.Emily@epa.gov), 202-564-4700

**Keala J. Hughes,**

Director of External Affairs & Tribal Relations, Gulf Coast Ecosystem Restoration Council.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2013-D-0446]

#### Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers." This guidance finalizes the revised draft guidance issued on November 2, 2022, and replaces the final guidance of the same title issued in June 2016 and updated in October 2017. The guidance addresses frequently asked questions, including those related to the implementation of FDA's regulations on expanded access to investigational drugs and other topics related to expanded access that are promulgated through the 21st Century Cures Act (Cures Act) and the FDA Reauthorization Act of 2017 (FDARA). Upon publication of this guidance, FDA is withdrawing the 1998 information sheet guidance, entitled "Emergency Use of an Investigational Drug or Biologic," for institutional review boards and clinical investigators because the information provided in the 1998 guidance is included in this final guidance.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 17, 2025.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the