FOR FURTHER INFORMATION CONTACT: Please send questions by email to Bridget Zachary by email *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.

[FR Doc. 2025–19981 Filed 11–14–25; 8:45 am]

BILLING CODE 6560–58–P

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,* 504–210–9982

Department of Interior

Blanchard, Mary Josie, Deputy Director, Environmental Protection Compliance, *MaryJosie_Blanchard@ios.doi.gov,* 202–208–3406

State of Florida

Blalock, Adam, Deputy Secretary for Ecosystem Restoration, *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,* 512–239–3900

Environmental Protection Agency

Fotouhi, David, Deputy Administrator, EPA, *Atkinson.Emily@epa.gov,* 202–564–4700

Keala J. Hughes,

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

[FR Doc. 2025–19987 Filed 11–14–25; 8:45 am]

BILLING CODE 6560–58–P

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

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0446 for ''Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dorothy West, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2500; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers.'' Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition (see section 561(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); 21 CFR 312.300(a)), rather than to obtain the kind of information about the drug that is generally derived from clinical trials. FDA issued a final guidance for industry in 2016 in a question-and-answer format to respond to the most frequently asked questions on various provisions of the regulation regarding expanded access. The 2016 guidance was updated in 2017.

Since the issuance of the updated final guidance in 2017, the Cures Act (Pub. L. 114–255) added section 561A to the FD&C Act (21 U.S.C. 360bbb–0) to include new requirements regarding expanded access. Under section 561A of the FD&C Act, a manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make its policy for evaluating and responding to expanded access requests (expanded access policy) readily available to the public, such as by posting the policy on a publicly available website. In addition, FDARA (Pub. L. 115–52) amended the FD&C Act to require that the expanded access policy for an investigational drug be posted by the earlier of (1) the first initiation of a phase 2 or phase 3 study with respect to such investigational drug or (2) within 15 days after the drug receives a fast track, breakthrough, or regenerative advanced therapy designation.

FDA issued a revised draft guidance of the same title on November 2, 2022 (87 FR 66191), to respond to questions received from interested parties since issuance of the updated final guidance in 2017. This guidance finalizes the revised draft guidance issued in November 2022 and includes the Agency's recommendations related to new requirements of the Cures Act and FDARA that pertain to expanded access. FDA considered comments received on the revised draft guidance as this guidance was finalized. Changes from the draft to the final guidance include additional clarifications related to informed consent and the process for submission of expanded access requests. In addition, we made editorial changes to improve clarity. FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers.'' It does

not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in part 312 (21 CFR part 312) and Form FDA 1571 have been approved under OMB control number 0910–0014. The collections of information in §§ 312.300 through 312.320 and Form FDA 3926 have been approved under OMB control number 0910–0814. The collections of information in 21 CFR part 201 have been approved under OMB control number 0910–0342. The collections of information in 42 CFR part 11 have been approved under OMB control number 0925–0586. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information pertaining to expedited programs for serious conditions for drugs have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–19984 Filed 11–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–5107]

Menstrual Products—Performance Testing and Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Menstrual Products—Performance Testing and Labeling Recommendations.'' This draft guidance document provides recommendations for performance testing, labeling, and information for inclusion in premarket notification (510(k)) submissions, when necessary, for certain menstrual products. The recommendations in this guidance apply to tampons, pads, and menstrual cups used to absorb or collect menstrual fluid or other vaginal discharge. The recommendations reflect updated review practices and are intended to promote consistency and transparency in product labeling and testing for manufacturers of these devices. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 16, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–D–5107 for ''Menstrual Products—Performance Testing and Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting