confidentiality of information provided by respondents to the FR 29b surveys will have to be determined on a case by case basis depending on the data collected under a particular survey. Some of the information collected on the surveys may be protected from Freedom of Information Act (FOIA) disclosure by FOIA exemptions 4 and 6. (5 U.S.C. 552 (b)(4) and (6)). Exemption 4 protects from disclosure trade secrets and commercial or financial information, while Exemption 6 protects information ''the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.''

*Consultation outside the agency:* Towers Watson and the Board work together to review and update the FR 29a survey instrument.

Board of Governors of the Federal Reserve System, June 26, 2017.

**Ann E. Misback**

*Secretary of the Board.*

[FR Doc. 2017–13641 Filed 6–28–17; 8:45 am]

**BILLING CODE 6210–01–P**

## GULF COAST ECOSYSTEM RESTORATION COUNCIL

**[Docket Number 106292017–1111–14]**

### Notice of Proposed Subaward Under a Council-Selected Restoration Component Award

**AGENCY:** Gulf Coast Ecosystem Restoration Council.

**ACTION:** Notice.

**SUMMARY:** The Gulf Coast Ecosystem Restoration Council (Council) publishes notice of a proposed subaward from the U.S. Department of Commerce (DOC), National Oceanic and Atmospheric Administration (NOAA) Restoration Center to The Nature Conservancy (TNC), a nonprofit organization, for the purpose of establishing the Gulf Coast Conservation Corps (GulfCorps) program to support meaningful Gulf of Mexico Habitat Restoration via Conservation Corps Partnerships as approved in the Initial Funded Priority List (FPL).

**FOR FURTHER INFORMATION CONTACT:** Please send questions by email to *raams_pgmsupport@restorethegulf.gov.*

**SUPPLEMENTARY INFORMATION:** Section 1321(t)(2)(E)(ii)(III) of the RESTORE Act (33 U.S.C. 1321(t)(2)(E)(ii)(III)) and Treasury's implementing regulation at 31 CFR 34.401(b) require that, for purposes of awards made under the Council-Selected Restoration Component, a State or Federal award recipient may make a grant or 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 provided to the State or Federal award recipient only if certain notice requirements are met. Specifically, at least 30 days before the State or Federal award recipient enters into such an agreement, the Council must publish in the **Federal Register** and deliver 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 accomplishes the **Federal Register** requirement.

**Description of Proposed Action**

As specified in the Initial FPL, which is available on the Council's Web site at *https://www.restorethegulf.gov/council-selected-restoration-component/funded-priorities-list,* RESTORE Act funds will support the Gulf of Mexico Habitat Restoration via Conservation Corps Partnerships, which is also referred to as the GulfCorps program. Through an interagency agreement with NOAA in the amount of $7,500,000, the GulfCorps program will contribute to meaningful Gulf Coast ecosystem restoration, while economically benefiting coastal communities by providing education, training, and opportunities to workers to implement conservation projects. The GulfCorps program will help establish partnerships among Federal, State, academic, and non-profit organizations to provide local labor for restoration projects; and will work through these partnerships to recruit, train, and employ workers to develop skills that will contribute to a local restoration-based workforce.

NOAA will coordinate development of the GulfCorps program in partnership with other Council members, as a means of creating a program that is reflective of Gulf priorities. NOAA will work within a collaborative process to prioritize projects with State partners and move forward on projects most supported by the respective State Council members, also considering synergies of pairing the GulfCorps program with other projects selected for the FPL, where appropriate. Through a proposed subaward to TNC in the amount of $7,000,000, TNC will recruit and train GulfCorps participants who will be mobilized to provide labor on selected coastal restoration projects in each Gulf State. Projects may include invasive species removal, shoreline protection and enhancement, riparian restoration, debris removal, re-vegetation, reef restoration, and habitat monitoring and conservation. TNC and their partners will provide training commensurate with the selected projects, as well as provide participants with soft skills that can help contribute to employability in restoration-based vocations.

**Will D. Spoon,**

*Program Analyst, Gulf Coast Ecosystem Restoration Council.*

[FR Doc. 2017–13633 Filed 6–28–17; 8:45 am]

**BILLING CODE 6560–58–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2003–D–0431]**

### Current Good Manufacturing Practice for Medical Gases; Draft 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 revised draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' This guidance is intended to assist manufacturers of medical gases in complying with applicable current good manufacturing practice (CGMP) regulations. Compliance with applicable CGMP requirements helps to ensure the safety, identity, strength, quality, and purity of medical gases. Medical gases that are not manufactured, produced, processed, packed, or held according to applicable CGMP requirements can cause serious injury or death. This guidance is expected to reduce the regulatory compliance burden for the medical gas industry by providing clear, up-to-date, detailed recommendations regarding CGMP issues that have been the subject of industry questions.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 28, 2017.

**ADDRESSES:** You may submit comments 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–2003–D–0431 for ''Current Good Manufacturing Practice for Medical Gases.'' 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.

• 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.gpo.gov/fdsys/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.

Submit written requests for single copies of the draft 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 draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Frank Perrella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4161, Silver Spring, MD 20993–0002, 301–796–3265.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' When finalized, this guidance will represent FDA's current thinking on the manufacture, processing, packing, and holding of medical gases in compliance with applicable CGMP regulations (21 CFR parts 210 and 211). This guidance does not address every potentially applicable CGMP requirement. Instead, it addresses those requirements that are considered most critical to the safety of medical gases, that have been the subject of industry questions, or for which FDA has otherwise determined compliance recommendations are appropriate.

FDA considered extensive input from the medical gas industry and other stakeholders regarding the appropriate application of CGMP requirements to medical gases in developing this revised draft guidance, which replaces the 2003 draft guidance of the same name (68 FR 24005, May 6, 2003). FDA carefully reviewed and considered comments submitted on the 2003 draft guidance, information from meetings with stakeholders, and relevant information from a review of Federal drug regulations as applied to medical gases.[1] FDA has changed draft recommendations regarding certain issues (*e.g.,* expiration dating for medical gases). As mentioned previously, this guidance does not address every potentially applicable CGMP requirement, and we note that if a regulation was cited in the 2003 draft guidance without further discussion, and FDA is not aware of a need for guidance on the issue, discussion of the requirement was generally omitted from this revised draft guidance.

We further note that this revised draft guidance is a key component of FDA's regulatory approach to medical gases. Section 1112 of the Food and Drug Administration Safety and Innovation Act (FDASIA) required that FDA determine whether any changes to Federal drug regulations were needed concerning medical gases, submit a report to Congress regarding any such changes, and undertake rulemaking to make any needed changes. In its report to Congress on this issue submitted in June 2015,[2] FDA explained its determination that, although some regulation changes were necessary to implement the medical gas labeling provisions contained in FDASIA,[3] the

[1] See section 1112(a)(2) of FDASIA(Pub. L. 112–144), requiring the review; see also FDA, 2015, ''Report to Congress, Review of Federal Drug Regulations With Regard to Medical Gases'', available at *https://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/UCM453727.pdf.*

[2] See FDA, 2015, ''Report to Congress, Review of Federal Drug Regulations With Regard to Medical Gases''.

[3] As amended by FDASIA, section 576(a)(3)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ddd–1(a)(3)(A)(ii)) provides that the requirements of sections 503(b)(4) of the FD&C Act (21 U.S.C. 353(b)(4)) (regarding labeling of a drug as a prescription drug) and 502(f) of the FD&C Act (21 U.S.C. 352(f)) (regarding inclusion of adequate directions for use and adequate warnings in drug labeling) are deemed to have been met for a designated medical gas if the labeling on the final use container for the medical gas bears: (1) The information required by section

current regulatory framework is adequate and sufficiently flexible to appropriately regulate medical gases. FDA further explained that it can continue to work within this framework to appropriately regulate these products.

FDA issued a final rule promulgating warning statements to be included in the labeling of designated medical gases on November 18, 2016 (81 FR 81685). This final rule also imposes labeling, design, and color requirements on medical gas containers and closures to increase the likelihood that the contents of medical gas containers are accurately identified and reduce the likelihood of the wrong gas being connected to a gas supply system or container. FDA may undertake additional targeted rulemaking in the future on other specific issues if FDA determines that such issues cannot be adequately addressed by other means.

In addition to the applicable regulations, FDA relies on guidance documents (such as this one), development of appropriate inspection practices and inspector training, and interaction with industry trade associations, State regulators, and other stakeholders on an as-needed basis in regulating medical gases.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on current good manufacturing practice for medical gases. 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

This revised draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

503(b)(4); (2) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and (3) appropriate directions and warnings concerning storage and handling.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 23, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–13608 Filed 6–28–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–3854]**

### Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices.'' The purpose of this workshop is to discuss potential scientific and regulatory challenges associated with developing traditional antimicrobial susceptibility testing (AST) devices and devices that detect antimicrobial resistance markers by molecular or novel diagnostic technologies, and to provide an overview of relevant provisions of the 21st Century Cures Act that may impact the development of such devices. Public input and feedback gained through this workshop will aid in the development of science-based approaches to regulatory decisionmaking regarding traditional and novel AST devices. Further, this workshop will explore opportunities for the efficient development and evaluation of AST devices, which may lead to better patient care and reduce antimicrobial resistance through improved antibiotic stewardship.

**DATES:** The public workshop will be held on September 13, 2017, from 8:30 a.m. to 5 p.m.

Submit either electronic or written comments on this public workshop by October 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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 public, 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