

Dated: July 5, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-14800 Filed 7-11-22; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-0277]

#### **Risk Management Plans To Mitigate the Potential for Drug Shortages; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Extension of Comment Period**

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability entitled “Risk Management Plans to Mitigate the Potential for Drug Shortages; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request” that appeared in the **Federal Register** on May 20, 2022. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the “Risk Management Plans to Mitigate the Potential for Drug Shortages; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request” published May 20, 2022 (87 FR 30963). Submit either electronic or written comments by August 31, 2022, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2022-D-0277 for “Risk Management Plans to Mitigate the Potential for Drug Shortages.” 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 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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

#### **FOR FURTHER INFORMATION CONTACT:**

*With regard to the draft guidance:* Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6686, Silver Spring, MD 20993-0002, 301-796-3191; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

*With regard to the proposed collection of information:* Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of May 20, 2022, FDA published a notice of availability with a 60-day comment period to provide comments on the draft guidance entitled "Risk Management Plans to Mitigate the Potential for Drug Shortages." FDA has received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is extending the comment period until August 31, 2022. The Agency believes that this extension allows adequate time for interested persons to submit comments.

**II. Electronic Access**

Persons with access to the internet may obtain an electronic version of the draft 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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 6, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-14809 Filed 7-11-22; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID 2022 DMID Omnibus BAA (HHS-NIH-NIAID-BAA2022-1)

Research Area 001: Development of Vaccine Candidates for Biodefense, Antimicrobial Resistant (AMR) Infections and Emerging Infectious Diseases (N01)-1.

*Date:* August 3-4, 2022.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20852, (240) 669-5023, [fdesilva@niaid.nih.gov](mailto:fdesilva@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 6, 2022.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022-14793 Filed 7-11-22; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Opportunities for Collaborative Research at the NIH Clinical Center.

*Date:* July 25, 2022.

*Time:* 11:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health,

6710B Rockledge Drive, Room 2127D, Bethesda, MD 20892 (Video Assisted Meeting).

*Contact Person:* Luis E. Dettin, Ph.D., MS, MA, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Rm. 2127D, Bethesda, MD 20892, (301) 827-8231, [luis\\_dettin@nih.gov](mailto:luis_dettin@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: July 6, 2022.

**David W. Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022-14791 Filed 7-11-22; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard**

[Docket No. USCG-2022-0206]

**Recertification of Cook Inlet Regional Citizens' Advisory Council**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of recertification.

**SUMMARY:** The Coast Guard announces the recertification of the Cook Inlet Regional Citizens' Advisory Council (CIRCAC) as an alternative voluntary advisory group for Cook Inlet, Alaska. This certification allows the CIRCAC to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990.

**DATES:** This recertification is effective for the period from September 1, 2022 through August 31, 2023.

**FOR FURTHER INFORMATION CONTACT:** For information about this document, call or email LT Lauren Bloch, Seventeenth Coast Guard District (dpi), by phone at (907) 463-2812 or email at [Lauren.E.Bloch@uscg.mil](mailto:Lauren.E.Bloch@uscg.mil).

**SUPPLEMENTARY INFORMATION:**