https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Ricky Soong at 301-348-1894.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Dated: May 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11385 Filed 5–27–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0455]

Revocation of Authorization of Emergency Use of a Medical Device During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Battelle Memorial Institute for the Battelle Critical Care Decontamination System. FDA revoked the Authorization on April 30, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by Battelle Memorial Institute on April 2, 2021. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization for the Battelle Critical Care Decontamination System is revoked as of April 30, 2021.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On March 28, 2020, FDA issued the Authorization to Battelle Memorial Institute for the Battelle Critical Care Decontamination System. Notice of the issuance of the Authorization was published in the **Federal Register** on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no

longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request for a Medical Device During COVID–19

On April 2, 2021, Battelle Memorial Institute requested the revocation of, and on April 30, 2021, FDA revoked, the Authorization for the Battelle Critical Care Decontamination System. Because Battelle Memorial Institute notified FDA that it has ceased operations and associated activities and requests withdrawal of the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/* and *https://www.fda.gov/media/148132/download.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for the Battelle Critical Care Decontamination System. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 30, 2021

Mr. Jeff Rose
Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201

Re: Revocation of EUA200210

Dear Mr. Rose:

This letter is in response to Battelle Memorial Institute's (Battelle's) request dated April 2, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA200210) for the Battelle Critical Care Decontamination System (hereafter referred to as "Battelle Decontamination System") issued on March 28, 2020, and revised and reissued on March 29, 2020, June 6, 2020, and January 21, 2021. In its request, Battelle confirmed that it has ceased operation of all Battelle Decontamination System sites as well as associated marketing activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Battelle has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA200210 for the Battelle Decontamination System, pursuant to and section 564(g)(2)(C) of the Act. As of the date of this letter, the Battelle Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Battelle to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: May 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11384 Filed 5–27–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Clinical Trials and Clinical Applications I.

Date: June 24, 2021.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer C Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20817, 240–276–5864, *jennifer.schiltz@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 24, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11294 Filed 5–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Clinical Trials and Clinical Applications II.

Date: June 28, 2021.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20817, 240–276–5864, *jennifer.schiltz@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 24, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11293 Filed 5–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0016]

Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act; Plans of Action To Respond to COVID–19

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) announces the formation of four Plans of Action under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic: Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19; Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19; Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19; and Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19. This notice contains the text of all four Plans of Action.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at *OB3I@fema.dhs.gov* or via phone at (202) 212–1666.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The Defense Production Act (DPA), 50 U.S.C. 4501 *et seq.,* authorizes the making of ''voluntary agreements and plans of action'' with, among others, representatives of industry and business to help provide for the national defense.[1] The President's authority to facilitate voluntary agreements was delegated to the Secretary of Homeland Security with respect to responding to the spread of COVID–19 within the United States in Executive Order 13911.[2] The Secretary of Homeland Security has further delegated this authority to the FEMA Administrator.[3]

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission and after requesting and considering public comments, FEMA completed and published in the **Federal Register** a ''Voluntary Agreement, Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a

[1] 50 U.S.C. 4558(c)(1).

[2] 85 FR 18403 (Apr. 1, 2020).

[3] DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).