website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 23, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 15, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 16, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Yu (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20733 Filed 9–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0973]

Revocation of Three Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of 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 Authorizations (EUAs) (the Authorizations) issued to Gravity Diagnostics, LLC (Gravity) for the Gravity Diagnostics COVID–19 Assay, Materials and Machines Corporation of America (DBA MatmaCorp, Inc.) (Matmacorp) for the MatMaCorp COVID–19 2SF Test, and Guardant Health Inc. (Guardant) for the Guardant-19. FDA revoked Gravity's Authorization on July 21, 2021, Matmacorp's Authorization on August 3, 2021, and Guardant's Authorization on August 6, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: Gravity's Authorization is revoked as of July 21, 2021. Matmacorp's Authorization is revoked as of August 3, 2021. Guardant's Authorization is revoked as of August 6, 2021.

ADDRESSES: Submit written requests for single copies of the revocations 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 revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

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 June 1, 2020, FDA issued an EUA to Gravity for the Gravity Diagnostics COVID–19 Assay. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On August 21, 2020, FDA issued an EUA to Guardant for the Guardant-19. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On December 17, 2020, FDA issued an EUA to Matmacorp, for the MatMaCorp COVID–19 2SF Test. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), 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 Requests

On March 11, 2021, and reconfirmed July 12, 2021, Gravity requested the revocation of, and on July 21, 2021, FDA revoked, the Authorization for the Gravity Diagnostics COVID–19 Assay. Because Gravity notified FDA that it is no longer using the Gravity Diagnostics COVID–19 Assay and requested FDA revoke the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On July 29, 2021, Matmacorp requested the revocation of, and on August 3, 2021, FDA revoked, the Authorization for the MatMaCorp COVID–19 2SF Test. Because Matmacorp notified FDA that it

will no longer be distributing the MatMaCorp COVID–19 2SF Test as of July 31, 2021, and requested FDA revoke the Authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On August 2, 2021, Guardant requested the revocation of, and on August 6, 2021, FDA revoked, the Authorization for the Guardant-19. Because Guardant requested that FDA revoke 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/, https://www.fda.gov/media/151030/download, https://www.fda.gov/media/151349/download,* and *https://www.fda.gov/media/151378/download.*

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs for Gravity's Gravity Diagnostics COVID–19 Assay, Matmacorp's MatMaCorp COVID–19 2SF Test, and Guardant's Guardant-19. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

July 21, 2021

James P. Canner Ph.D.
VP, Regulatory, Clinical, and Research Programs
Gravity Diagnostics, LLC
632 Russell Street
Covington, KY 41011
Re: Revocation of EUA200031

Dear Dr. Canner:

This letter is in response to Gravity Diagnostics, LLC's (Gravity's) email request originally received March 11, 2021, and reconfirmed July 12, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200031) for the Gravity Diagnostics COVID-19 Assay issued on June 1, 2020, and amended on June 30, 2020, and September 21, 2020. Gravity confirmed that it is no longer using the Gravity Diagnostics COVID-19 Assay at Gravity's laboratory, having transitioned to another EUA-authorized test.

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 circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Gravity has notified FDA that it is longer using the Gravity Diagnostics COVID-19 Assay and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200031 for the Gravity Diagnostics COVID-19 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Gravity Diagnostics COVID-19 Assay is no longer authorized for emergency use by FDA.

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

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

August 3, 2021

Dustin Petrik, Ph.D.
Regulatory Liaison
Materials and Machines Corporation of America (DBA MatmaCorp, Inc.)
6400 Cornhusker Hwy, Suite 300
Lincoln, NE 68507

Re: Revocation of EUA202648

Dear Dr. Petrik,

This letter is in response to MatmaCorp, Inc.'s (Matmacorp) request dated July 29, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA202648) for the MatMaCorp COVID-19 2SF Test issued on December 17, 2020. In its July 29 letter, Matmacorp requested revocation of the MatMaCorp COVID-19 2SF Test effective July 31, 2021.

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 circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Matmacorp has notified FDA that it will no longer be distributing the MatMaCorp COVID-19 2SF Test as of July 31, 2021, and requests FDA revoke the authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202648 for MatMaCorp COVID-19 2SF Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MatMaCorp COVID-19 2SF Test is no longer authorized for emergency use by FDA.

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

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

August 6, 2021

Dr. Katie Bessette
Sr. Director, Regulatory Affairs
Guardant Health, Inc.
505 Penobscot Drive
Redwood City, CA 94063

Re: Revocation of EUA201847

Dear Dr. Bessette,

This letter is in response to Guardant Health Inc.'s (Guardant) request, dated August 2, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA201847) for Guardant-19 issued on August 21, 2020 and amended on December 28, 2020. In its August 2 letter, Guardant requested revocation of the Guardant-19 effective July 16, 2021.

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 circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Guardant has requested that FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201847 for Guardant-19, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Guardant-19 is no longer authorized for emergency use by FDA.

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

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20754 Filed 9–23–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0897]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on December 2, 2021, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://*