DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting—FSYX Ocular Pressure Adjusting Pump System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on March 21, 2024, from 9 a.m. to 6 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Akinola Awojope, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Akinola.Awojope@fda.hhs.gov,* 301–636–0512, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On March 21, 2024, the committee will discuss and make recommendations on information related to the De Novo request by Balance Ophthalmics, Inc. for the safety and effectiveness of the FSYX Ocular Pressure Adjusting Pump (FSYX OPAP) System. The FSYX OPAP System is indicated as adjunctive therapy for the reduction of intraocular pressure (IOP) during use in adult patients with open-angle glaucoma and IOP ≤21 mmHg.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the 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 and select 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. Written submissions may be made to the contact person on or before March 5, 2024. Oral presentations from the public will be scheduled on March 21, 2024, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 February 26, 2024. 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 February 27, 2024.

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 AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 240–507–6496 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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: February 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02361 Filed 2–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Device 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 Authorization (EUAs) (the Authorizations) issued to Southern California Permanente Medical Group, for the Kaiser Permanente High Throughput SARS–CoV–2 Assay, that

includes the Kaiser Permanente Saliva Home Collection Kit, and Drexel University College of Medicine, for the SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorization for the Southern California Permanente Medical Group's Kaiser Permanente High Throughput SARS–CoV–2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, is effective as of September 29, 2023. The revocation of the Authorization for the Drexel University College of Medicine for the SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay is effective as of October 5, 2023.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or 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 April 19, 2021, FDA issued the Authorization to Southern California Permanente Medical Group, for the Kaiser Permanente High Throughput SARS–CoV–2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040), as required by section 564(h)(1) of the FD&C Act.

On April 28, 2023, FDA issued the Authorization to Drexel University College of Medicine, for the SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on January 25, 2024 (89 FR 4952), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorizations were made available on FDA's website. 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. Authorizations Revocation Requests

In a request received by FDA on May 11, 2023, Southern California Permanente Medical Group requested the withdrawal of, and on September 29, 2023, FDA revoked, the Authorization for the Southern California Permanente Medical Group's Kaiser Permanente High Throughput SARS–CoV–2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit. Because Southern California Permanente Medical Group notified FDA that they have stopped distributing the Kaiser Permanente Saliva Home Collection Kit at the end of May 2023 and have also stopped receiving and processing the kits and requested FDA withdraw the Southern California Permanente Medical Group's Kaiser Permanente High Throughput SARS–CoV–2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on September 29, 2023, Drexel University College of Medicine requested the withdrawal of, and on October 5, 2023, FDA revoked, the Authorization for the Drexel University College of Medicine's SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay. Because Drexel University College of Medicine notified FDA that they have discontinued the use of SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay at Drexel University, Drexel Medicine Diagnostics and requested FDA withdraw the Drexel University College of Medicine's SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay, 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/.*

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 EUA of Southern California Permanente Medical Group's Kaiser Permanente High Throughput SARS–CoV–2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, and Drexel University College of Medicine's SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay. The revocation in its entirety follows and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4161–01–P

U.S. FOOD & DRUG ADMINISTRATION

September 29, 2023

Kenneth Van Horn, PhD, D(ABMM)
Technical Director, Microbiology
Southern California Permanente Medical Group
Regional Reference Laboratories, Chino Hills
13000 Peyton Drive
Chino Hills, CA 91709

Re: Revocation of EUA203058

Dear Dr. Van Horn:

This letter is in response to the request from Southern California Permanente Medical Group, in a letter received May 11, 2023, that the U.S. Food and Drug Administration (FDA) terminate the EUA for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, issued on April 19, 2021 and subsequently re-issued on September 21, 2021. Southern California Permanente Medical Group indicated that they have stopped distributing the Kaiser Permanente Saliva Home Collection Kit at the end of May 2023 and have also stopped receiving and processing the kits as of the date of this letter, and requested that the EUA be terminated.

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 Southern California Permanente Medical Group has requested that FDA terminate the EUA for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203058 for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Kaiser Permanente High Throughput SARS-CoV-2 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

October 5, 2023

Donald C. Hall, Jr. Ph.D.
Director of Operations
Drexel Medicine Diagnostics
College of Medicine, Drexel University
245 N. 15th Street, Room 5108
Philadelphia, PA 19102

Re: Revocation of EUA220099

Dear Dr. Hall:

This letter is in response to the request from Drexel University College of Medicine, in an email received September 29, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, issued on April 19, 2021. Drexel University College of Medicine indicated that they have discontinued use of the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay at Drexel University, Drexel Medicine Diagnostics, located at 245 N. 15th Street, Room 5401, Philadelphia, PA 19102.

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 Drexel University College of Medicine has requested that FDA withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220099 for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DUCoM-PDL Modified Tetracore 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Date: February 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02356 Filed 2–5–24; 8:45 am]

BILLING CODE 4161–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1031]

Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; 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 ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability.'' This guidance addresses the process through which registrants of drug establishments should submit reports to FDA on the amount of each listed drug manufactured, prepared,