Collection identifier: FR 3064.

OMB control number: 7100–0344.

General description of collection: The Debit Card Issuer Survey (FR 3064a) collects data from issuers of debit cards (including general-use prepaid cards) that, together with their affiliates, have assets of $10 billion or more, including information regarding the volume and value of debit card transactions; chargebacks and returns; costs of authorization, clearance, and settlement of debit card transactions; other costs incurred in connection with particular debit card transactions; fraud prevention costs and fraud losses; and interchange fee revenue. The Payment Card Network Survey (FR 3064b) collects data from payment card networks, including the volume and value of debit card transactions; interchange fees; network fees; and payments and incentives paid by networks to acquirers, merchants, and issuers.

The data from the FR 3064a and FR 3064b are used to fulfill a statutory requirement that the Board disclose certain information regarding debit card transactions on a biennial basis. In addition, the Board uses data from the Payment Card Network Survey (FR 3064b) to publicly report on an annual basis the extent to which networks have established separate interchange fees for exempt and covered issuers.

Frequency: Annual.

Respondents: Debit card issuers and payment card networks.

Total estimated number of respondents: FR 3064a, 531; FR 3064b, 15.

Estimated average hours per response: FR 3064a, 160; FR 3064b, 75.

Total estimated annual burden hours: FR 3064a, 84,960; FR 3064b, 1,125.

Board of Governors of the Federal Reserve System, May 23, 2025.

Benjamin W. McDonough,

Deputy Secretary and Ombuds of the Board.

[FR Doc. 2025–09662 Filed 5–28–25; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Four 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 Pfizer Inc. for the Lucira COVID–19 All-In-One Test Kit and Lucira CHECK–IT COVID–19 Test Kit, MAWD Laboratories for the MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR, and Nuclein, LLC (merged with Molecular Diagnostics Inc.) for the DASH SARS–CoV–2/S Test. 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 Pfizer Inc.'s Lucira COVID–19 All-In-One Test and Lucira CHECK–IT COVID–19 Test Kit was effective as of April 2, 2025, MAWD Laboratories' MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR was effective as of April 2, 2025, and Nuclein, LLC's (following merger with Molecular Diagnostics Inc.) DASH SARS–CoV–2/S Test was effective as of April 3, 2025.

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 November 17, 2020, FDA issued the Authorization to Lucira Health, Inc. for the Lucira COVID–19 All-In-One Test Kit, subject to the terms of the Authorization.[1] 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.

On April 9, 2021, FDA issued the Authorization to Lucira Health, Inc. for the Lucira CHECK√IT COVID–19 Test Kit, subject to the terms of the Authorization.[2] 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 October 13, 2023, FDA issued the Authorization to MAWD Laboratories for the MAWD Laboratories' SARS–CoV–2 Dual Target by RT–PCR, 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.

On March 15, 2022, FDA issued the Authorization to Minute Molecular Diagnostics, Inc. (merged with Nuclein, LLC) for the DASH SARS–CoV–2/S Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 22, 2022 (87 FR 43877), 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 March 14, 2025, Pfizer Inc. requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira COVID–19 All-In-One Test Kit. Pfizer Inc. notified FDA that it did not distribute the Pfizer Inc.'s

[1] Ownership of the EUA for the Lucira COVID–19 All-In-One Test Kit was transferred from Lucira Health, Inc. to Pfizer Inc.

[2] Ownership of the EUA for the Lucira CHECK–IT COVID–19 Test Kit was transferred from Lucira Health, Inc. to Pfizer Inc.

Lucira COVID–19 All-In-One Test Kit, and requested FDA revoke the Pfizer Inc.'s Lucira COVID–19 All-In-One Test 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 March 14, 2025, Pfizer Inc., requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira CHECK–IT COVID–19 Test Kit. Pfizer Inc. notified FDA that it did not distribute the Pfizer Inc.'s Lucira CHECK–IT COVID–19 Test Kit, and requested FDA revoke the Pfizer Inc.'s Lucira CHECK–IT COVID–19 Test 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 March 17, 2025, MAWD Laboratories requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the MAWD Laboratories' MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR. MAWD Laboratories notified FDA that it had discontinued use of the MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR as of April 2, 2025, and requested FDA revoke the MAWD Laboratories' MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR. 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 March 17, 2025, Nuclein, LLC (following merger with Minute Molecular Diagnostics, Inc.), requested the revocation of, and on April 3, 2025, FDA revoked, the Authorization for the Nuclein, LLC's DASH SARS–CoV–2/S Test. Nuclein, LLC notified FDA that it had ceased manufacture of the authorized Nuclein, LLC's DASH SARS–CoV–2/S Test as of January 1, 2025, and requested FDA revoke the Nuclein, LLC's DASH SARS–CoV–2/S Test. 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 Pfizer Inc.'s Lucira CHECK-IT COVID–19 Test Kit and Lucira COVID–19 All-In-One Test Kit, MAWD Laboratories' MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR, and Nuclein, LLC's DASH SARS–CoV–2/S Test. The revocations in their entirety follow and provide 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 2, 2025

Elizabeth Mauro
Director, Global Regulatory Science
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001
Re: Revocation of EUA202920

Dear Elizabeth Mauro:
This letter is in response to the request from Pfizer Inc., in letter dated March 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira COVID-19 All-In-One Test Kit issued on November 17, 2020, amended on September 23, 2021, and July 28, 2022, and revised and reissued on November 15, 2022, and June 14, 2023. Pfizer Inc. indicated that they did not distribute the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Lucira COVID-19 All-In-One Test Kit reagents in distribution in the United States.

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 Pfizer Inc. has requested that FDA revoke the EUA for the Lucira COVID-19 All-In-One Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202920 for the Lucira COVID-19 All-In-One Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira COVID-19 All-In-One Test Kit 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

April 2, 2025

Elizabeth Mauro
Director, Global Regulatory Science
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001
Re: Revocation of EUA210196

Dear Elizabeth Mauro:
This letter is in response to the request from Pfizer Inc., in letter dated March 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira CHECK-IT COVID-19 Test Kit issued on April 9, 2021, amended on September 23, 2021, July 28, 2022, and December 12, 2022, and revised and reissued on June 29, 2023. Pfizer Inc. indicated that they did not distribute the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Lucira CHECK-IT COVID-19 Test Kit reagents in distribution in the United States.

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 Pfizer Inc. has requested that FDA revoke the EUA for the Lucira CHECK-IT COVID-19 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210196 for the Lucira CHECK-IT COVID-19 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira CHECK-IT COVID-19 Test Kit 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 2, 2025

Philip Adam, Ph.D., HCLD/CC(ABB)
MAWD Pathology Group, P.A.
Infectious Diseases Section Director
MAWD Laboratories
11070 Strang Line Rd.
Lenexa, KS 66215

Re: Revocation of EUA210691

Dear Dr. Adam:

This letter is in response to the request from MAWD Laboratories, in a letter received March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR issued on October 13, 2023. MAWD Laboratories indicated that as of the date of this letter they have discontinued use of the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR test at MAWD Laboratories, located at 11070 Strang Line Rd., Lenexa, KS 66215.

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 MAWD Laboratories has requested that FDA revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210691 for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 3, 2025

Steve Back
Chief Operating Officer
Nuclein, LLC
8305 Cross Park Drive
Austin, TX 78754
Re: Revocation of EUA210603

Dear Steve Back:

This letter is in response to the request from Nuclein, LLC (following Nuclein, LLC's December 27, 2024, merger with, and assumption of responsibility for, the original EUA holder, Minute Molecular Diagnostics, Inc.), in a letter dated March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the DASH SARS-CoV-2/S Test issued on March 15, 2022, and amended on July 28, 2022. Nuclein, LLC indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable DASH SARS-CoV-2/S Test reagents remaining in distribution in the United States.

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 Nuclein, LLC has requested that FDA revoke the EUA for the DASH SARS-CoV-2/S Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210603 for the DASH SARS-CoV-2/S Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DASH SARS-CoV-2/S 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09678 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5302]

Michael Dominic Diaz: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Michael Dominic Diaz for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Diaz was convicted of one felony count under Federal law. The factual basis supporting Mr. Diaz's conviction, as described below, is conduct relating