Warning Plans for Cigarettes and Smokeless Tobacco Products'' on September 9, 2011, which describes the information and format to be submitted for smokeless plans (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-warning-plans-cigarettes-and-smokeless-tobacco-products*). Submitters may also visit a web page that describes the smokeless tobacco labeling and warning statement requirements (*https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements*). Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan. Warning plans can be submitted either electronically or in paper format. The Center for Tobacco Products (CTP) Portal, available at *https://ctpportal.fda.gov/ctpportal/login.jsp,* provides a secure online system for electronically submitting documents and receiving messages from CTP.

Based on our experience with the information collection over the past 3 years, we retain our estimate of 60 hours to complete an initial rotational plan. We estimate half this time for preparing and submitting a supplement to an approved plan (30 hours).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of initial rotational plans for health warning statements	1	1	1	60	60
Supplement to approved plan	4	1	4	30	120
Total					180

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates a total of 1 respondent will submit a new original warning plan yearly and take 60 hours to complete a rotational warning plan for a total of 60 burden hours. In addition, FDA estimates a total of 4 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 120 hours. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. Therefore, we have decreased our estimate burden by 360 hours.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09885 Filed 5–6–22; 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 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 Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit and to Applied DNA Sciences, Inc., for the Linea COVID–19 Assay Kit. FDA revoked these Authorizations 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: The Authorization for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit is revoked as of April 15, 2022. The Authorization for the Linea COVID–19 Assay Kit is revoked as of April 20, 2022.

ADDRESSES: Submit written requests for a single copy 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) 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, 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 February 11, 2021, FDA issued an EUA to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, subject to the terms of the Authorization. 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 May 13, 2020, FDA issued an EUA to Applied DNA Sciences, Inc. for the Linea COVID–19 Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), 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. EUA Revocation Requests

In a request received by FDA on March 17, 2022, Bio-Rad Laboratories, Inc., requested revocation of, and on April 15, 2022, FDA revoked, the Authorization for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit. Because Bio-Rad Laboratories, Inc. notified FDA that it has ceased U.S. distribution of the Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on April 7, 2022, Applied DNA Sciences, Inc., requested revocation of, and on April 20, 2022, FDA revoked, the Authorization for the Linea COVID–19 Assay Kit. Because Applied DNA Sciences, Inc. notified FDA that it has decided to discontinue distribution of the Linea COVID–19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID–19 Assay Kit, FDA 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 Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, and Applied DNA Sciences, Inc., for the Linea COVID–19 Assay Kit. 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

April 14, 2022

Elizabeth Platt EdD, MS, MBA
Sr. Director, Regulatory & Clinical Affairs | Americas
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 92647
Re: Revocation of EUA202965

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., received via email on March 17, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA, with an effective date of April 15, 2022, for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit issued on February 11, 2021, and amended on September 23, 2021. Bio-Rad Laboratories, Inc. ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit on March 2, 2022, and has discontinued this assay.

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 Bio-Rad Laboratories, Inc. has notified FDA that it has ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, per your request, effective April 15, 2022, FDA hereby revokes EUA202965 for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. Effective as of April 15, 2022, the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay 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/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 20, 2022

Clay D. Shorrock, Esq.
Chief Legal Officer and Exec. Dir., Business Development
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790
Re: Revocation of EUA200474

Dear Mr. Shorrock:

This letter is in response to the request from Applied DNA Sciences, Inc., received on April 7, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Linea COVID-19 Assay Kit issued on May 13, 2020, re-issued on May 11, 2021, and amended on July 8, 2020, July 30, 2020, September 25, 2020, November 21, 2020, July 21, 2021, and September 23, 2021. Applied DNA Sciences, Inc. indicated that it is no longer distributing or utilizing the Linea COVID-19 Assay Kit. Applied DNA Sciences, Inc. has transitioned to the use of the Linea 2.0 COVID-19 Assay and other EUA-authorized tests.

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 Applied DNA Sciences, Inc. has notified FDA that it has decided to discontinue distribution of the Linea COVID-19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID-19 Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200474 for the Linea COVID-19 Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Linea COVID-19 Assay 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/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: James A. Hayward, Ph.D., Chairman, President & CEO, Applied DNA Sciences, Inc.

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09887 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1112]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 8, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitary Program

OMB Control Number 0910–0021—Extension

Under section 243 of the Public Health Service Act (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the U.S. molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitors its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish dealers to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate'' (available at *https://www.fda.gov/media/72094/download*). FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List (ICSSL),'' a monthly comprehensive listing of all molluscan shellfish dealers certified under the cooperative program (available at *https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list*). If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and prevent the distribution in the United States of shellfish processed by uncertified dealers. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the ICSSL, the effectiveness of the NSSP would be nullified. The ICSSL is also used to identify U.S. shellfish dealers eligible to obtain health certificates and export to certain countries or regions.

FDA has been collecting information to construct the ICSSL since 2001. FDA is seeking to add one new data field to Form FDA 3038, the ''FDA Establishment Identifier'' (FEI number). The FEI number is a unique number assigned by FDA to identify FDA-regulated facilities. FDA will explore whether the FEI can be used to retrieve data on shellfish dealers from existing FDA systems, which could reduce the number of required data elements that firms have to submit on Form FDA 3038.

The information collection also includes providing certain documents demonstrating compliance with the NSSP. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for molluscan shellfish are equivalent to their system of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. FDA uses this information to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter is in compliance with the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission's (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union's (EU) system of controls, the EC is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities with firms seeking to export raw molluscan shellfish to the EU. This documentation includes, but is not limited to:

- A list of growing areas with an Approved classification;
- the most recent sanitary survey for each growing area with an Approved classification; and
- the most recent inspection report for each firm seeking to export shellfish to the EU.

Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We plan to provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Description of Respondents: Respondents to this collection are participating State and local regulatory agencies and foreign nations.