

“REGISTER FOR NSAC MEETING” in the subject line. The deadline for members of the public to register to attend the meeting in-person is Tuesday, May 9, at 5 p.m. eastern. Members of the public are encouraged to submit registration requests via email in advance of the deadline, as space is limited and will be available on a first-come, first-served basis for those who register in advance. We will note when the limit of in-person attendees has been reached. The meeting will also stream live via a link on the Federal Maritime Commission’s website, [www.fmc.gov](http://www.fmc.gov). If technical issues prevent the Commission from live streaming, the Commission will post a recording of the meeting on the FMC’s YouTube channel.

**FOR FURTHER INFORMATION CONTACT:** Mr. Dylan Richmond, Designated Federal Officer of the National Shipper Advisory Committee, phone: (202) 523-5810; email: [drichmond@fmc.gov](mailto:drichmond@fmc.gov).

**SUPPLEMENTARY INFORMATION:**

*Background:* The National Shipper Advisory Committee is a federal advisory committee. It operates under the provisions of the Federal Advisory Committee Act, 5 U.S.C. app., and 46 U.S.C. chapter 425. The Committee was established on January 1, 2021, when the National Defense Authorization Act for Fiscal Year 2021 became law. Public Law 116-283, section 8604, 134 Stat. 3388 (2021). The Committee provides information, insight, and expertise pertaining to conditions in the ocean freight delivery system to the Commission. Specifically, the Committee advises the Federal Maritime Commission on policies relating to the competitiveness, reliability, integrity, and fairness of the international ocean freight delivery system. 46 U.S.C. 45202(b).

The Committee will receive an update from each of its subcommittees. The Committee may receive proposals for recommendations to the Federal Maritime Commission and may vote on these recommendations. Any proposed recommendations will be available for the public to view in advance of the meeting on the NSAC’s website, <https://www.fmc.gov/industry-oversight/national-shipper-advisory-committee/>.

*Public Comments:* Members of the public may submit written comments to NSAC at any time. Comments should be addressed to NSAC, c/o Dylan Richmond, Federal Maritime Commission, 800 North Capitol St. NW, Washington, DC 20573 or [nsac@fmc.gov](mailto:nsac@fmc.gov).

The Committee will also take public comment at its meeting. If attending the

meeting in person and providing comments, please note that in the registration request. Comments are most helpful if they address the Committee’s objectives or their proposed recommendations. Comments at the meeting will be limited to 3 minutes each.

A copy of all meeting documentation, including meeting minutes, will be available at [www.fmc.gov](http://www.fmc.gov) following the meeting.

By the Commission.

Dated: April 14, 2023.

**William Cody,**

*Secretary.*

[FR Doc. 2023-08318 Filed 4-19-23; 8:45 am]

**BILLING CODE 6730-02-P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than May 22, 2023.

*A. Federal Reserve Bank of San Francisco* (Joseph Cuenco, Assistant Vice President, Formations & Transactions and Enforcement) 101

Market Street, San Francisco, California 94105. Comments can also be sent electronically to [sf.fisc.comments.applications@sf.frb.org](mailto:sf.fisc.comments.applications@sf.frb.org).

1. *Lexicon Bancorp*; to become a bank holding company by acquiring Lexicon Bank, both of Las Vegas, Nevada.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2023-08388 Filed 4-19-23; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-0940]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of rapid response surveys to obtain data on safety information that supports quick turnaround decision making about potential safety problems or risk management solutions.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 20, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2023-N-0940 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** JennaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### Rapid Response Surveys

#### OMB Control Number 0910-0500—Extension

This generic information collection supports research conducted by FDA, as authorized under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA is requesting extension of OMB approval to conduct rapid response surveys. Through these surveys, FDA seeks to determine whether a problem impacts the public health and to quickly obtain vital information about risks and interventions. FDA will use the information gathered from these surveys to make quick turnaround decisions about safety problems or risk management solutions so the Agency may take appropriate public health action including dissemination of information as necessary. Participation in these surveys is voluntary.

Respondents may include manufacturers and distributors of biologics, drugs, food, animal food and drugs, dietary supplements, food additives, cosmetics, medical devices, and tobacco products; distributors; sponsors and importers; consumers; healthcare professionals; hospitals; specialized medical facilities (e.g., cardiac surgery, obstetrics/gynecology services, pediatric services, etc.) and other user facilities including nursing homes, ambulatory surgical and outpatient diagnostic and treatment facilities when FDA must quickly determine whether or not a problem impacts the public health. Once FDA understands the need for additional surveillance data to address a potential public health hazard, the appropriate

respondents will be identified for each unique rapid response survey.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Surveys .....	10,000	1	10,000	0.5 (30 minutes) .....	5,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that each rapid response survey will take no more than 30 minutes to complete.

Based on a review of the information collection since our last request, we have adjusted our burden estimate which has resulted in a decrease to the currently approved burden. We now estimate one response per respondent which results in a decrease in overall burden of 25,000 hours.

Dated: April 14, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-08297 Filed 4-19-23; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-1378]

#### Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of Ebola; 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 (EUs) (the Authorizations) issued to BioFire Defense, LLC, for the FilmArray NGDS BT-E Assay, and Biocartis NV, for the Idylla Rapid Ebola Virus Triage Test. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each 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 BioFire Defense, LLC's FilmArray NGDS BT-E Assay is effective as of March 8, 2023. The revocation of the Authorization for the Biocartis NV's Idylla Rapid Ebola Virus

Triage Test is effective as of March 9, 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, 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 October 25, 2014, FDA issued the Authorization to BioFire Defense, LLC, for the FilmArray NGDS BT-E Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on February 9, 2015 (80 FR 6972), as required by section 564(h)(1) of the FD&C Act. On May 26, 2016, FDA issued the Authorization to Biocartis NV, for the Idylla Rapid Ebola Virus Triage Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was

published in the **Federal Register** on July 8, 2016 (81 FR 44616), 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. Authorization Revocation Requests

In a request received by FDA on February 24, 2023, BioFire Defense, LLC, requested the revocation of, and on March 8, 2023, FDA revoked, the Authorization for the BioFire Defense, LLC's FilmArray NGDS BT-E Assay. Because BioFire Defense, LLC, notified FDA that it is obsolescing the FilmArray NGDS BT-E Assay and requested FDA withdraw the BioFire Defense, LLC's, FilmArray NGDS BT-E Assay, 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 November 23, 2022, Biocartis US, Inc., on behalf of Biocartis NV, requested rescission of, and on March 9, 2023, FDA revoked, the Authorization for the Idylla Rapid Ebola Virus Triage Test. Because Biocartis US, Inc., on behalf of Biocartis NV, notified FDA that it has discontinued the production of Idylla Rapid Ebola Virus Triage Test and requested FDA rescind the Authorization for the Idylla Rapid Ebola Virus Triage 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/>.