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 [1]

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

[1] 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 (EUAs) (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/.*

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 BioFire Defense, LLC's FilmArray NGDS BT-E Assay and of Biocartis NV's Idylla Rapid Ebola Virus Triage Test. 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 4161–01–P

March 8, 2023

David Rabiger, PhD
Associate Director of Regulatory and Clinical Affairs
BioFire Defense, LLC
79 W 4500 S, Suite 14
Salt Lake City, Utah 84107

Re: Revocation of EUA140009

Dear Dr. Rabiger:

This letter is in response to the request from BioFire Defense, LLC, received via email on February 24, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the FilmArray NGDS BT-E Assay issued on October 25, 2014, amended on November 22,2014, and December 2, 2015, and reissued on March 2, 2015. BioFire Defense, LLC indicated that they are obsolescing the FilmArray NGDS BT-E Assay, that it is no longer commercially available, and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there is no viable FilmArray NGDS BT-E Assay 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 BioFire Defense, LLC has requested FDA withdraw the EUA for the FilmArray NGDS BT-E Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA140009 for the FilmArray NGDS BT-E Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the FilmArray NGDS BT-E 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/

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

March 9, 2023

Sue Werner
Head of Regulatory Affairs
Biocartis US, Inc.
Two Pierce Place, Suite 1510
Itasca, IL 60143

Re: Revocation of EUA160008

Dear Sue Werner:

This letter is in response to the request from Biocartis US, Inc., on behalf of Biocartis NV, in a letter received November 23, 2022, that the U.S. Food and Drug Administration (FDA) rescind the EUA for the Idylla Rapid Ebola Virus Triage Test issued on May 26, 2016. Biocartis US, Inc. indicated that Biocartis has discontinued production of the authorized product, has no plans to re-initiate production, and has requested that the EUA be rescinded. FDA understands that no Idylla Rapid Ebola Virus Triage Test reagents associated with this EUA are being produced or are available to the United States market.

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. has requested FDA rescind the EUA 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. Accordingly, FDA hereby revokes EUA160008 for the Idylla Rapid Ebola Virus Triage Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Idylla Rapid Ebola Virus Triage 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/

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

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08281 Filed 4–19–23; 8:45 am]

BILLING CODE 4161–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1146]

Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment; 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 draft guidance for industry entitled ''Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment.'' The purpose of this draft guidance is to provide information and recommendations to assist sponsors and other interested parties in the development of drugs to prevent or treat acute radiation syndrome (ARS) caused by exposure to ionizing radiation from accidental or deliberate events. Generally, drugs developed for such indications will require approval under