Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Interviews with program directors	18	1	1.5	27	9
Interviews with caseworkers	36	1	1	36	12
Focus groups with residents	105	1	1.5	157.5	52.5
Self-sufficiency matrix	680	3	1.5	3,060	1,020
Service receipt questionnaire	680	3	.25	510	170
2023 Version—Semi-Annual Quantitative Report Mandatory Form	3	4	3	36	12
2024 Version—Semi-Annual Quantitative Report Mandatory Form	15	3	3	135	45
2023 Version—Semi-Annual Quantitative Report Optional Form	1	4	3	12	4
2024 Version—Semi-Annual Report Optional Form	5	3	3	45	15
Quarterly Narrative PPR	18	6	2	216	72

Estimated Total Annual Burden Hours: 1,411.5.

Authority: Section 1110, Social Security Act, 42 U.S.C. 1310.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–19695 Filed 8–30–24; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Authorization 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 (EUA) (the Authorization) issued to Roche Molecular Systems, Inc, for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the Roche Molecular Systems, Inc.'s for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit is effective as of July 3, 2024.

ADDRESSES: Submit written requests for a single copy of the revocation 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

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 September 14, 2020, FDA issued the Authorization to Roche Molecular Systems, Inc, for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorization 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 Request

In a request received by FDA on June 21, 2024, Roche Molecular Systems, Inc., requested the revocation of, and on July 3, 2024, FDA revoked, the Authorization for the Roche Molecular Systems, Inc.'s cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit. Because Roche Molecular Systems, Inc., notified FDA that they have ceased the manufacture and distribution of the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit and requested FDA revoke Roche Molecular Systems, Inc.'s, cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit, 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 Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Roche Molecular Systems, Inc.'s cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

July 3, 2024

Aradhana Karthikeyan
Senior Manager Regulatory Affairs
RA Functional Partner, molecular PoC
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: Revocation of EUA201779

Dear Aradhana Karthikeyan:

This letter is in response to the request from Roche Molecular Systems, Inc., in a letter dated June 21, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, issued on September 14, 2020, and revised on September 18, 2020, November 19, 2020, December 10, 2020, May 7, 2021, May 14, 2021, June 24, 2021, September 23, 2021, January 6, 2022, March 25, 2022, August 11, 2022, October 26, 2022, February 16, 2023 and June 16, 2023.

Roche Molecular Systems, Inc. indicated that they have ceased the manufacture and distribution of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System reagents for the EUA labeled product, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, and requested that the EUA be revoked. As of the date of this letter Roche Molecular Systems, Inc., has fully transitioned to the cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System product that was cleared under K223591.

FDA understands that as of the date of this letter Roche Molecular Systems, Inc. has ceased the manufacture and distribution of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System reagents, that also includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, for the EUA labeled product, but that there remains some viable EUA labeled product 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 Roche Molecular Systems, Inc. has requested that FDA revoke the EUA for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201779 for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the cobas SARS-CoV-2 & Influenza A/B

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nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, is no longer authorized for emergency use by FDA.

As discussed, FDA does not have concerns with the use of any remaining viable inventory of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, that is the EUA labeled product and that was distributed prior to revocation of the EUA, when such product is used in conjunction with the cleared package insert/manufacturer instructions for use cleared as part of the July 27, 2023 510(k) cleared cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System . Importantly, the cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System product for which FDA had issued an EUA and the product for which FDA has cleared under 510(k) are manufactured under the same quality system with the same lot release criteria. Roche Molecular Systems, Inc. should instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System EUA labeled product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance issued on July 27, 2023. Roche Molecular Systems, Inc. should also instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023 and that the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA labeled product inventory may also be used in combination with the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System product, which FDA has cleared under 510(k). FDA encourages Roche Molecular Systems, Inc. to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of this EUA revocation and provide access to the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023.

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: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19724 Filed 8–30–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3904]

Identifying Priority Focus Areas for Future Guidance Development and Engagement With Interested Parties in Model-Informed Drug Development; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for Information.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) within the Food and Drug Administration (FDA or Agency) are announcing a request for information (RFI) for advancing model-informed drug development (MIDD). The purpose of this request is to obtain feedback on how to increase application of established MIDD approaches in regulatory decision making, to identify how emerging MIDD approaches are being incorporated within drug product development, and to identify opportunities to enhance interactions with FDA when discussing MIDD approaches. We intend to use the information submitted in response to this request to identify and prioritize potential focus areas for future policy or guidance development and enhance engagement with interested parties, including interactions as part of the