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: Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0260, *compounding@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 1, 2026, FDA published a notice with a 60-day comment period to request comments on FDA's proposal not to include semaglutide, tirzepatide, or liraglutide on the 503B Bulks List. Comments on the proposal will inform FDA's final determination whether to include these substances on the 503B Bulks List.

The Agency has received a request for a 60-day extension of the comment period for the May 1, 2026 **Federal Register** notice. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the **Federal Register** notice. The request states that the additional time will allow interested parties to develop rigorous and comprehensive comments that will address complex clinical, public health, and legal issues; engage thoughtfully with a complicated regulatory landscape; and thoroughly address issues around patient safety and access to high-quality medications.

FDA has considered the request and is extending the comment period for the **Federal Register** notice for 30 days, until July 30, 2026. The Agency believes that a 30-day extension, rather than 60 days, appropriately balances allowing adequate time for interested persons to submit comments with avoiding significant delay of Agency action on these important issues. FDA encourages comments to address the clinical need standard provided by the statute and FDA's rationale in the May 1, 2026 **Federal Register** notice.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12937 Filed 6–25–26; 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 Three 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 Becton, Dickinson and Company (BD) for the BD Veritor System for Rapid Detection of SARS–CoV–2, InBios International, Inc. for the SCoV–2 *Detect* Neutralizing Ab ELISA, and Roche Diagnostics for the Elecsys Anti-SARS–CoV–2. 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 Authorizations for the Becton, Dickinson and Company's BD Veritor System for Rapid Detection of SARS–CoV–2 was effective as of February 24, 2026, InBios International, Inc.'s SCoV–2 *Detect* Neutralizing Ab ELISA was effective as of February 24, 2026, and Roche Diagnostics's Elecsys Anti-SARS–CoV–2 was effective as of March 2, 2026.

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. 5441, 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 July 2, 2020, FDA issued the Authorization to Becton, Dickinson and Company (BD) for the BD Veritor System for Rapid Detection of SARS–CoV–2, 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.

On October 22, 2021, FDA issued the Authorization to InBios International, Inc. for the SCoV–2 *Detect* Neutralizing Ab ELISA, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on March 22, 2022 (87 FR 16196), as required by section 564(h)(1) of the FD&C Act.

On May 2, 2020, FDA issued the Authorization to Roche Diagnostics for the Elecsys Anti-SARS–CoV–2, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (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. Authorizations Revocation Requests

In a request received by FDA on January 29, 2026, Becton, Dickinson and Company requested the withdrawal of, and on February 24, 2026, FDA revoked, the Authorization for the Becton, Dickinson and Company's BD Veritor System for Rapid Detection of SARS–CoV–2. BD notified FDA as the date of the letter there are no viable BD Veritor System for Rapid Detection of SARS–CoV–2 reagents remaining in distribution in the United States, and requested FDA withdraw the Becton, Dickinson and Company's BD Veritor System for Rapid Detection of SARS–CoV–2. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization given that BD has fully transitioned to the BD Veritor System for SARS–CoV–2 product cleared under K243872.

In a request received by FDA on February 16, 2026, InBios International, Inc. requested the revocation of, and on February 24, 2026, FDA revoked, the Authorization for the InBios International, Inc.'s SCoV–2 *Detect* Neutralizing Ab ELISA. FDA understands that as the date of the letter there are no viable SCoV–2 *Detect* Neutralizing Ab ELISA reagents remaining in distribution in the United States, and InBios International, Inc. requested FDA revoke its SCoV–2 *Detect* Neutralizing Ab ELISA. 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 February 6, 2026, Roche Diagnostics requested the revocation of, and on March 2, 2026, FDA revoked, the Authorization for the Roche Diagnostics's Elecsys Anti-SARS–CoV–2. FDA understands that as the date of the letter there are no viable Elecsys Anti-SARS–CoV–2 reagents remaining in distribution in the United States, and requested FDA revoke the Roche Diagnostics's Elecsys Anti-SARS–CoV–2. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization given that Roche Diagnostics has fully transitioned to the Elecsys Anti-SARS–CoV–2 product cleared under K250768.

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 for Becton, Dickinson and Company's BD Veritor System for Rapid Detection of SARS–CoV–2, InBios International, Inc.'s SCoV–2 *Detect* Neutralizing Ab ELISA, and Roche Diagnostics's Elecsys Anti-SARS–CoV–2. 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

February 24, 2026

David Lee
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Integrated Diagnostic Solutions – Point of Care
7 Loveton Circle
Sparks, MD 21152
Re: Revocation of EUA201889

Dear David Lee:
This letter is in response to the request from Becton, Dickinson and Company ("BD"), in a letter dated January 29, 2026, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Veritor System for Rapid Detection of SARS-CoV-2 issued on July 2, 2020, revised and reissued on January 13, 2021, and March 31, 2021, and amended on July 23, 2020, December 10, 2021, November 1, 2022, and March 21, 2023. FDA understands that as of the date of this letter there are no viable BD Veritor System for Rapid Detection of SARS-CoV-2 reagents remaining in distribution in the United States. As of the date of this letter, BD has fully transitioned to the BD Veritor System for SARS-CoV-2 product that was cleared under K243872.

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 BD has requested that FDA withdraw the EUA for the BD Veritor System for Rapid Detection of SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201889 for the BD Veritor System for Rapid Detection of SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Veritor System for Rapid Detection of SARS-CoV-2 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//

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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

February 24, 2026

Estela Raychaudhuri
President
InBios International, Inc.
307 Westlake Avenue N, Suite 300
Seattle, WA 98109

Re: Revocation of EUA210540

Dear Estela Raychaudhuri:

This letter is in response to the request from InBios International, Inc., in an email dated February 16, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SCoV-2 *Detect* Neutralizing Ab ELISA issued on October 22, 2021. FDA understands that as of the date of this letter there is no viable SCoV-2 *Detect* Neutralizing Ab ELISA 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 InBios International, Inc. has requested that FDA revoke the EUA for the SCoV-2 *Detect* Neutralizing Ab ELISA, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210540 for the SCoV-2 *Detect* Neutralizing Ab ELISA, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SCoV-2 *Detect* Neutralizing Ab ELISA 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

March 2, 2026

Tammy Dean
Senior Regulatory Affairs Manager
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Re: Revocation of EUA200514

Dear Tammy Dean:
This letter is in response to the request from Roche Diagnostics, in an email dated February 6, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Elecsys Anti-SARS-CoV-2 issued on May 2, 2020, revised and reissued on May 19, 2021, and amended on June 4, 2020, July 21, 2020, October 23, 2020, July 13, 2021, September 23, 2021, and December 17, 2021. FDA understands that as of the date of this letter there are no viable EUA Elecsys Anti-SARS-CoV-2 reagents remaining in distribution in the United States. As of the date of this letter, Roche Diagnostics has fully transitioned to the Elecsys Anti-SARS-CoV-2 product that was cleared under K250768.

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 Diagnostics has requested that FDA revoke the EUA for the Elecsys Anti-SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200514 for the Elecsys Anti-SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Elecsys Anti-SARS-CoV-2 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

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–12906 Filed 6–25–26; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5827]

Agency Information Collection Activities; Proposed Collection; Comment Request; Time and Extent Applications for Nonprescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 time and extent