Rider Trail South, Earth City, MO 63045.

If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981. This phone number is only for questions about courier delivery.

Note that the address for payments made by mail has not changed and should continue to be mailed to:

- *CQA and MDUFA:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.
- *For BsUFA, FSMA, and GDUFA:* Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.
- *For PDUFA:* Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If a check, bank draft, or U.S. postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). The FDA post office box number must be written on the check, bank draft, or U.S. postal money order.

In addition, note that the information for payments made by wire transfer has not changed, and must include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should continue to be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. (Note: Invoice copies do not need to be submitted to FDA with the payments.)

Dated: September 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21989 Filed 10–3–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4180]

Revocation of Authorization of Emergency Use of Becton, Dickinson and Company Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site); 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 Becton, Dickinson and Co., for the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site). FDA revoked this 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 in this document.

DATES: The Authorization for the Becton, Dickinson and Co., BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) is revoked as of July 11, 2023.

ADDRESSES: Submit a written request 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 July 22, 2021, FDA issued the Authorization to Becton, Dickinson and Co., for the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59738), 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 12, 2023, Becton, Dickinson and Co. requested the withdrawal of, and on July 11, 2023, FDA revoked the Authorization for the Becton, Dickinson and Co.'s BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site). Because Becton, Dickinson and Co., notified FDA that they have discontinued the sale of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) and requested FDA withdraw the EUA for the Becton, Dickinson and Co.'s BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), 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 revocation is 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 Becton, Dickinson and Co.'s BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site). 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.

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July 11, 2023

Matthew Trachtenberg, MSE
Director Regulatory Affairs
Becton, Dickinson and Co.
1 Becton Drive
Franklin Lakes, NJ 07417

Re: Revocation of EUA210465

Dear Matthew Trachtenberg:

This letter is in response to the request from Becton, Dickinson and Co. ("BD"), in an email received June 12, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) issued on July 22, 2021. BD indicated that they have discontinued the sale of the authorized product and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, there are no viable BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) 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 BD has requested that FDA withdraw the EUA for the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA210465 for the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) are 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: September 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21995 Filed 10–3–23; 8:45 am]

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