FOR FURTHER INFORMATION CONTACT: Joan Dailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–6357, *Joan.Dailey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ULTRAM (tramadol hydrochloride) Tablets, 50 mg, is the subject of NDA 020281, held by Janssen Pharmaceuticals, Inc., and initially approved on March 3, 1995. ULTRAM is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

ULTRAM (tramadol hydrochloride) Tablets, 50 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated June 28, 2023 (Docket No. FDA–2023–P–2656), under 21 CFR 10.30, requesting that the Agency determine whether ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was withdrawn from sale for reasons of safety or effectiveness. The citizen petition noted that FDA has already determined that the 100 mg tablet strength of the same drug was not discontinued for reasons of safety or effectiveness (see the **Federal Register** of April 27, 2022 (87 FR 25028)).

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ULTRAM (tramadol hydrochloride) Tablets, 50 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ULTRAM (tramadol hydrochloride) Tablets, 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21990 Filed 10–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4158]

User Fee Rates for Fiscal Year 2024; Change of Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that the courier address for the U.S. Bank will change. This change has a direct impact on the Fiscal Year 2024 **Federal Register** notices for the following FDA User Fee programs: Prescription Drug User Fee Amendments (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User Fee Amendments (GDUFA), Biosimilar User Fee Amendments (BsUFA), Food Safety Modernization Act (FSMA), and Compounding Quality Act (CQA). The new physical address will be 3180 Rider Trail South, Earth City, MO 63045.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62080, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this notice is to inform the public that the physical address for overnight packages for the U.S. Bank will change on October 6, 2023. The building's street address has changed from 1005 Convention Plaza, St. Louis, MO 63101, to 3180 Rider Trail South, Earth City, MO 63045. The last date to use the old address to deliver a check by courier, such as Federal Express or UPS, is October 5, 2023, and payers must use the new address for any packages beginning October 6, 2023, to prevent any disruption to the processing of their overnight package payments. Note that this new address is for courier delivery only.

If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:

- *For CQA and MDUFA:* U.S. Bank, ATTN: Government Lockbox 979033, 3180 Rider Trail South, Earth City, MO 63045.
- *For BsUFA, FSMA, and GDUFA:* U.S. Bank, ATTN: Government Lockbox 979108, 3180 Rider Trail South, Earth City, MO 63045.
- *For PDUFA:* U.S. Bank, ATTN: Government Lockbox 979107, 3180

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]

BILLING CODE 4164–01–P

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