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 BD indicated that they have discontinued the sale of the authorized product and requested that the EUA be withdrawn.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,

_____

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