

December 2, 2022

Beth Lingenfelter  
VP of Clinical and Regulatory Affairs  
Visby Medical, Inc.  
3010 North First Street  
San Jose, CA 95134

**Re: Revocation of EUA203089**

Dear Ms. Lingenfelter:

This letter is in response to the request from Visby Medical, Inc., received via email on November 29, 2022, that the U.S. Food and Drug Administration (FDA) close the EUA for the Visby Medical COVID-19 Point of Care Test issued on February 8, 2021, amended on September 23, 2021, and reissued on July 22, 2022. Visby Medical, Inc. discontinued manufacturing the Visby Medical COVID-19 Point of Care Test on April 25, 2022, and FDA understands there are no viable (non-expired) Visby Medical COVID-19 Point of Care Tests 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 Visby Medical, Inc. has requested FDA close the EUA for the Visby Medical COVID-19 Point of Care Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203089 for the Visby Medical COVID-19 Point of Care Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Visby Medical COVID-19 Point of Care Test 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,

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Namandjé N. Bumpus, Ph.D.  
Chief Scientist  
Food and Drug Administration