

August 3, 2021

Dustin Petrik, Ph.D. Regulatory Liaison Materials and Machines Corporation of America (DBA MatmaCorp, Inc.) 6400 Cornhusker Hwy, Suite 300 Lincoln, NE 68507

Re: Revocation of EUA202648

Dear Dr. Petrik,

This letter is in response to MatmaCorp, Inc.'s (Matmacorp) request dated July 29, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA202648) for the MatMaCorp COVID-19 2SF Test issued on December 17, 2020. In its July 29 letter, Matmacorp requested revocation of the MatMaCorp COVID-19 2SF Test effective July 31, 2021.

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 Matmacorp has notified FDA that it will no longer be distributing the MatMaCorp COVID-19 2SF Test as of July 31, 2021, and requests FDA revoke the authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202648 for MatMaCorp COVID-19 2SF Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MatMaCorp COVID-19 2SF 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration