

Hennepin County Medical Center Department of Emergency Medicine 701 Park Avenue, #MC-825 Minneapolis, Minnesota 55415-1623

Dear

We acknowledge receipt of your correspondence dated June 4, 2021, in response to our letter of May 5, 2021, regarding observations made during our inspection conducted between April 9 and April 23, 2019.

We trust that the actions described in your letter will provide adequate measures to bring your site into compliance with FDA regulations. Any written response and all correspondence will be included as a permanent part of your file.

Should you have any questions or concerns regarding this letter or the inspection, please write to me at the address given below.

Sincerely,

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Miah N. Jung Digitally signed by Miah N. Jung-S DN: c=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Miah N. Jung -S, 0.9.2342.19200300.100.1.1=2000935.735 Date: 2021.10.06.08:14:18-04'00'

Miah Jung, Pharm.D., M.S. Branch Chief (Acting) Compliance Enforcement Branch Division of Enforcement and Postmarketing Safety Office of Scientific Investigations Office of Compliance Center for Drug Evaluation and Research U.S. Food and Drug Administration Building 51, Room 5219 10903 New Hampshire Avenue Silver Spring, MD 20993