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

Dear [Redacted]:

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,

Miah N. Jung

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
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