Hennepin County Medical Center
Department of Emergency Medicine
701 Park Avenue
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 10 and April 26, 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
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5219
10903 New Hampshire Avenue
Silver Spring, MD 20993