



E-MAIL

Accelaron Pharma, Inc.
Attention: James V. Desiderio, Ph.D.
128 Sidney Street
Cambridge, Massachusetts 02139

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2020-110
NCT01727336

Dear Dr. Desiderio:

On April 27, 2021, the Food and Drug Administration (FDA) sent your company a Notice of Noncompliance regarding the requirements to submit clinical trial information to the ClinicalTrials.gov data bank. At this time, it appears that your company has addressed the issues raised in FDA's letter.

Sincerely,

{See appended electronic signature page}

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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/s/

LAURIE B MULDOWNEY
12/13/2021 10:01:05 AM