

E-MAIL

Andrey Petrikovets, M.D. 1513 South Grand Avenue, Suite 400 Los Angeles, California 90015

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)

FDA Reference Number: CDER-2020-109

NCT03052816

Dear Dr. Petrikovets:

On August 31, 2021, the Food and Drug Administration (FDA) sent you a Notice of Noncompliance regarding the requirements to submit clinical trial information to the ClinicalTrials.gov data bank. At this time, it appears that you have addressed the issues raised in FDA's letter.

Sincerely,

Laurie B. Digitally signed by Laurie B. Muldowney -S

Date: 2021.12.20

Muldowney -S Date: 2021.12.20 10:30:16 -05'00'

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