

VIA E-MAIL

Ocugen

Attention: Vijay Tammara, Ph.D. Senior Vice President, Global Regulatory and Quality 263 Great Valley Parkway Malvern, Pennsylvania 19355

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

FDA Reference Number: CDER-2021-126

NCT03785340

Dear Dr. Tammara:

On April 18, 2022, the Food and Drug Administration (FDA) sent your company a Notice of Noncompliance, dated April 15, 2022, 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 08/01/2022 09:07:44 AM