

Food and Drug Administration Silver Spring, MD 20993

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December 17, 2021

Sent electronically

Mr. Ellison, Mr. Gibbs, Ms. Javitt, and Mr. Shumsky,

This letter responds to your Information Quality Request for Correction pertaining to information that appears on FDA's website under the heading SARS-CoV-2 Reference Panel Comparative Data https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

This request is still under review. FDA's goal is to respond to such request within 60 days. We are unable to do so in this case. We anticipate a response will be sent to you by February 15, 2022.

Sincerely,

Laurie Lenkel FDA Ombudsman