



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Hyman, Phelps & McNamara, P.C.
C/O Gail Javitt
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929
G.Javitt@hpm.com

April 24, 2023

Sent electronically

RE: Information Quality Act Challenge 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> 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>

Dear Mistrs: Ellison, Gibbs, Shumsky, and Ms. Javitt,

FDA last wrote to you on February 23, 2023, indicating that additional time would be needed to complete a response to your Request for Correction regarding the above mentioned matter. The agency continues to work on that response. We anticipate a response will be sent to you within 60 days.

Sincerely,

A handwritten signature in cursive script that reads "L. Lenkel".

Laurie Lenkel
FDA Ombudsman