



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
GJavitt@hpm.com

August 20, 2021

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

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

Your December 22, 2020, request for correction of information disseminated via the Food and Drug Administration's (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>, is still under review. While the goal of the FDA is to respond within 60 days to such requests, we are unable to do so in this case. We anticipate a response will be sent to you by October 18, 2021.

Thank you for your interest in the quality of information disseminated by FDA.

Sincerely,

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

Laurie Lenkel
FDA Ombudsman