



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

October 19, 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>

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

Your December 22, 2020, Information Quality Request for Correction listed above, is still under review. Competing priorities have not allowed us to respond within 60 days as is our goal. We anticipate a response will be sent to you by December 17, 2021.

Thank you for your interest in the quality of information disseminated by the Food and Drug Administration.

Sincerely,

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

Laurie Lenkel
FDA Ombudsman