

Food and Drug Administration Silver Spring, MD 20993

February 15, 2022

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

Sent electronically

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

RE: 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 letter is an interim response to your December 22, 2020, request for correction of information pursuant to the Federal Information Quality Act. Your request is currently under review.

While our goal is to respond within 60 days to such requests, we are unable to do so in this case. We anticipate providing you with a response by April 15, 2022.

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

Sincerely,

Laurie Lenkel FDA Ombudsman

L. Lenkel