DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 22, 2021

Hyman, Phelps & McNamara, P.C.
c/o Gail H. Javitt
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Regarding: 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

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

This letter is an interim response to your request for correction of information pursuant to the Federal Information Quality Act, HHS Information Quality Guidelines, and the FDA's Guidelines for Ensuring the Quality of Information Disseminated to the Public.

FDA's information quality guidance, which is part of the Department of Health and Human Services Guidelines for Ensuring the Quality of Information Disseminated to the Public, states that FDA will respond to an Information Quality Challenge within 60 days, either by issuing a decision or by providing an estimated decision date.

We have not yet completed our response to your Request for Correction. We anticipate providing you with a response by April 23, 2021.

Sincerely,

L. Lenkel

Laurie Lenkel
FDA Ombudsman