DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

April 15, 2022

Hyman, Phelps & McNamara
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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-medicaldevices/sars-cov-2-reference-panel-comparative-data

This letter is an interim response to your December 22, 2020, request for correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub.L. No.106-554, 114 Stat. 2763A-153 (2000) (the Federal Data Quality Act).

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 complaint within 60 days, either by issuing a decision or by providing you with an estimated decision date.

We have not yet completed our response to your request for reconsideration. We anticipate providing you with a response within 60 days from the date of this letter.

Sincerely,

L. Lenkel

Laurie Lenkel
FDA Office of the Ombudsman