U.S. FOOD & DRUG ADMINISTRATION

November 29, 2022

Allen K. Murray, Ph.D.
[redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-1065

Dear Dr. Murray:

This is an interim response to the petition dated June 7, 2022, filed by the Food and Drug Administration (FDA) on June 8, 2022, and the amendment dated September 20, 2022, filed by FDA on September 22, 2022. In the petition as amended, you requested FDA issue a regulation to ban the use of glycogen assays that employ centrifugation of homogenates of patient specimens and only use the supernatant of such centrifugation for the amyloglucosidase degradation of glycogen in the assay.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Ms. Gugandeep Kaur by e-mail at gugandeep.kaur@fda.hhs.gov or 240-402-9534.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2022.11.29 11:31:48 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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