U.S. FOOD & DRUG ADMINISTRATION

September 27, 2023

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

Sent via email: [redacted]

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

Dear Dr. Murray,

This letter responds to the above referenced citizen petition, received and processed by the U.S. Food and Drug Administration (FDA or Agency) on June 8, 2022, and the amendment, received and processed by FDA on September 22, 2022. In your petition and subsequent amendment, you request that the 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." In accordance with 21 CFR § 10.30(e), and for the reasons set forth below, your petition is denied.

A. Requested Action

Your petition and subsequent amendment present information intended to support your request that the Agency 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. In your petition, you state "[t]he centrifugation removes a significant amount of glycogen resulting in an inaccurate determination of glycogen." Your petition further states that, "[t]he result is that we now have several hundred published papers with inaccurate glycogen data," and that "[t]here are at least 12 companies that are selling such [glycogen] kits and the stock market analysts project significant growth for the market through 2028. . . I believe that something should be done to remove such defective assay kits from the marketplace." In your amendment you state that "any procedure involving a centrifugation of the homogenate and assay of only the supernatant is not going to produce a result of the total glycogen." Your amendment also further specified your requested action was a ban by FDA of "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." You clarified that "[t]his does not apply if the method employs treatment of the homogenate in KOH at elevated temperature followed by alcohol precipitation of the glycogen before amyloglucosidase degradation."

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B. Discussion

FDA has reviewed the information you submitted, as well as other information already available to the Agency, and is denying your petition for two reasons. First, under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), products are regulated as devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or when they are intended to affect the structure or any function of the body. FDA's regulations specify that the term "intended use" or similar words "refer[s] to the objective intent of the persons legally responsible for the labeling of an article (or their representatives)."[1] That intent "may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article."[2]

Based on the information you submitted, as well as other information we have reviewed, it appears that the glycogen assays you referenced in Appendix 1 of your citizen petition are not intended for clinical use or for human or veterinary diagnostic or therapeutic use and, instead, are intended for use in research of glycogen levels in biological samples.[3] While we acknowledge your assertion that biological samples tested with these glycogen assays may consist of human tissue,[4] this alone is insufficient to conclude that these assays are devices under the FD&C Act and its implementing regulations.

Second, the FD&C Act authorizes FDA to promulgate a regulation banning a device only where, on the basis of all available data and information, FDA finds that the device "presents substantial deception or an unreasonable and substantial risk of illness or injury," where such deception or risk cannot be or has not been "corrected or eliminated by labeling or change in labeling."[5] In determining whether a deception or risk of illness or injury is substantial, FDA "will consider whether the deception or risk posed by the continued marketing of the device . . . is important, material, or significant in relation to the benefit to the public health from its continued marketing."[6]

As noted above, the information on glycogen kits you reference in your petition does not provide us enough information to determine whether these kits meet the definition of a device under the FD&C Act and its implementing regulations. Even assuming that these products are devices, FDA has carefully reviewed the information you submitted, and finds it insufficient to support a finding that 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 present a substantial deception or an unreasonable and substantial risk of illness or injury under the FD&C Act and its implementing regulations. We find you did not provide

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[1] See 21 CFR 801.4

[2] *Id.*

[3] The websites for the glycogen assay kits you identified in Appendix 1 of your citizen petition claim the kits are for uses such as "Research Use Only", "Not For Use In Humans", "Not For Human Or Veterinary Diagnostic Or Therapeutic Use" and "Not For Use In Diagnostic Procedures."

[4] In your petition, you cite at least one article that used "human muscle samples" in a glycogen assay experiment. *See* Petition, p.2. However, this research article used the assays to establish a control condition for measuring muscle glycogen content after high-intensity exercise, not for a diagnostic or clinical purpose.

[5] Section 516(a)(1) of the FD&C Act, 21 U.S.C. 360f(a)(1); 21 CFR 895.21(a).

[6] 21 CFR 895.21(a)(1).

sufficient information to assess whether there is substantial deception from these glycogen assays. Your petition and subsequent amendment explain alleged manufacturing problems with glycogen assay kits through several published scientific articles. However, none of these articles provides evidence of substantial deception from commercially available glycogen assay kits. Additionally, we find you did not provide sufficient information to support a finding of unreasonable and substantial risk of illness or injury, primarily because the use of these glycogen assays is intended to be limited to research use only. These glycogen assays are not intended for diagnostic use or to inform or drive clinical decision making. The patient population, therefore, is not impacted by these glycogen assays or the results derived from them.

Accordingly, we find that there is insufficient information in your petition to conclude that the implicated glycogen assay kits are devices subject to the FD&C Act and its implementing regulations. Further, we find that, even if these kits are devices, the statutory standard for a device ban is not met and FDA declines to initiate rulemaking to ban 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.

C. Conclusion

For the reasons discussed above, FDA is denying your petition.

If you have any questions, 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: 2023.09.27 12:56:02 -04'00'

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