June 8, 2020

John Coleman, M.A., M.S., PH.D.
(b) (6)
[redacted]

Re: Citizen Petition – Docket Number FDA-2020-P-1003

Dear Dr. Coleman:

This is an interim response to the petition dated February 25, 2020, filed by the Food and Drug Administration (FDA) on February 28, 2020. In the petition, you requested:

1. The fever thermometer industry has changed significantly since 1997 when the FDA issued its guidance document for convenience kits that exempted them from premarket clearance by the agency. In view of this and the proliferation of U.S. and foreign-made infrared thermometers, it is requested that the FDA initiate rulemaking procedures to require premarket clearance for all models of fever thermometers sold OTC in the U.S.
2. The FDA rulemaking for fever thermometers should include certification of the technology used by the device's sponsor as well as the accuracy and safety of the device intended for marketing in the U.S.
3. It is further requested that all fever thermometers currently marketed in the U.S. be subject to the proposed rule and meet the requirements thereof in order to be permitted for marketing in the U.S.

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 Joshua Chetta of our Office of Policy at (240) 402-4910

Sincerely yours,

Ellen J. Flannery -S
Digitally signed by Ellen J. Flannery -S
Date: 2020.06.08 18:12:10 -04'00'

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