DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 2, 2020

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

Sent via email to: (b) (6) [redacted]

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA the following:

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.

Your Submission was received by this office on 02/28/2020, and it has been assigned docket number FDA-2020-P-1003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby Digitally signed by Dynna Bigby Date: 2020.03.03 11:38:46 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)