

JOHN J. COLEMAN, M.A., M.S., PH.D.

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Citizen Petition

February 25, 2020

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Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room, 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: A Citizens Petition requesting the Food and Drug Administration (FDA) to issue a rule regulating the marketing of fever thermometers sold over-the-counter.

Dear Sir or Madam:

The undersigned, Dr. John J. Coleman, acting on behalf of himself as an individual citizen, submits this petition to request that the FDA issue a rule regulating the marketing of fever thermometers as safe and effective when used as directed. Currently, fever thermometers are marketed over-the-counter (OTC) by pharmacies, grocery stores, mail order suppliers, and other retailers.

A webpage published on February 15, 2020 by the Centers for Disease Control and Prevention (CDC) listed “fever” as the first of three symptoms (along with cough and shortness of breath) of the coronavirus disease 2019 (COVID-19). These are common symptoms of all viral infections and typically during flu season are monitored by individuals in a home setting.

Two general types of fever thermometers are marketed to the public. The mercury thermometer, although considered accurate, has been slowly removed from the market because of concerns about the toxicity of mercury. Since 2001, about 20 states have banned these thermometers and the U.S. government no longer calibrates them for accuracy.

In essence, today’s personal fever thermometer market consists almost exclusively of the second type of fever thermometer, the electronic or battery-driven infrared thermometer.

Infrared thermometers come in various forms, some requiring surface contact and some that use laser or beam technology to take a reading. Most of today’s fever thermometers are manufactured in China. A recent query using the expression “fever thermometer” returned a list of over 1,000 individual products being marketed on Amazon.com, a major online retailer of these popular medical devices.

On February 3, 2020, the undersigned purchased two infrared thermometers from Amazon.com, each identified as “Mosen Thermometer for Fever, Baby Thermometer, Ear and Forehead Thermometer, Thermometer for Kid and Adult, Digital Infrared Thermometro [sic] for Body, Surface and Room, with Magnetic Cap [2020 New Version].” Each cost \$36.99.

The Mosen Thermometer, according to the packaging, is manufactured by the Shenzhen AOJ Medical Technology Co., Ltd in Shenzhen, China. The packaging displays several certification labels issued by regulatory agencies in Europe (“EC REP” and “CE 0123” and “RoHS”). There are no U.S. certifications of regulatory compliance because none is required.

The undersigned tested both Mosen thermometers and found them to differ with each other by as much as 5 degrees over several tests using the infrared procedures described in a small instruction booklet that accompanied each thermometer. The undersigned has attached to this petition copies of the packaging for the two Mosen thermometers purchased via Amazon.com.

Besides the inaccuracy of these thermometers, the undersigned found that the instruction booklet accompanying them was confusing and misleading and could easily cause someone to misuse the device. For example, in a paragraph titled, “How to use your thermometer,” we find the following advice: “Please make sure that the device will be used in the room only, and there is no strong conversation of wind.”

According to an FDA guidance document titled “Convenience Kits Interim Regulatory Guidance,” dated May 1997, a “fever monitoring kit” (i.e., fever thermometer) is identified as a “convenience kit” for regulatory purposes. It appears in a list of convenience kits not required to obtain premarket clearance from the FDA. In publishing this guidance document, the FDA stated: “Based on this experience, FDA believes that under certain circumstances premarket clearance for convenience kits may not be necessary to ensure protection of the public health.”

A. Action 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.

B. Statement of Grounds

According to the CDC, the primary way that viral infections, including the COVID-19, appears to spread is by close person-to-person contact. Isolation of infected persons is considered the most effective means of preventing and reducing the spread of the virus. The CDC advises that viral infections like the COVID-19 often begins with a fever greater than 38°C (100.4°F). Many individuals likely will rely on an infrared fever thermometer to monitor their health. It is essential to protect the public health that these personal devices, identified by the FDA as “convenience kits” be accurate to within a standard that minimizes false positives.

The FDA has the legal authority to regulate fever thermometers. The agency’s decision as reflected in its 1997 guidance document to exempt convenience kits, including fever thermometers, was characterized at the time as “discretionary.” While this choice may have been appropriate for 1997, the petitioner believes that the time has come and the circumstances demand that FDA immediately revisit this decision and reverse it by enacting a rule to regulate the marketing of fever thermometers in the U.S. in a manner that ensures their accuracy and safety.

The current design of the infrared thermometer was not available for outpatient use until about 2002 – some five years after the FDA exempted what then was mostly a mercury thermometer industry from regulatory control under section 510(k) of the Federal Food, Drug, and Cosmetic Act.

Finally, that other authorities, including European nations and the European Union, have chosen to regulate fever thermometers should encourage U.S. authorities to adopt similar regulations to protect the U.S. public health.

C. Environment Impact

Petitioner claims a categorical exclusion under 21 C.F.R. §25.34.

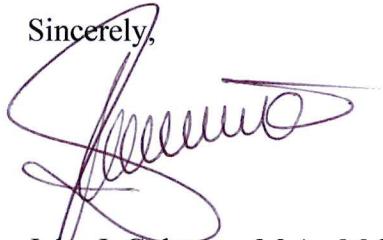
D. Economic Impact Statement

Petitioner, upon request by the Commissioner, will submit an economic impact statement under 21 C.F.R. § 10.30(b)(3).

E. Certification

The undersigned petitioner, Dr. John J. Coleman, certifies to the best of his knowledge and belief that this petition contains all the information and views on which this petition relies, and that it includes representative data and information known to the petitioner that are both favorable and unfavorable to the petition. The petitioner has no conflicts of interest in preparing or submitting this petition for the action requested, and the ideas, facts, and representations made in this petition are solely those of the petitioner who has neither sought nor received assistance or input for this petition from anyone else.

Sincerely,



John J. Coleman, M.A., M.S., Ph.D.

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w/attachment





2/27/2020

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