



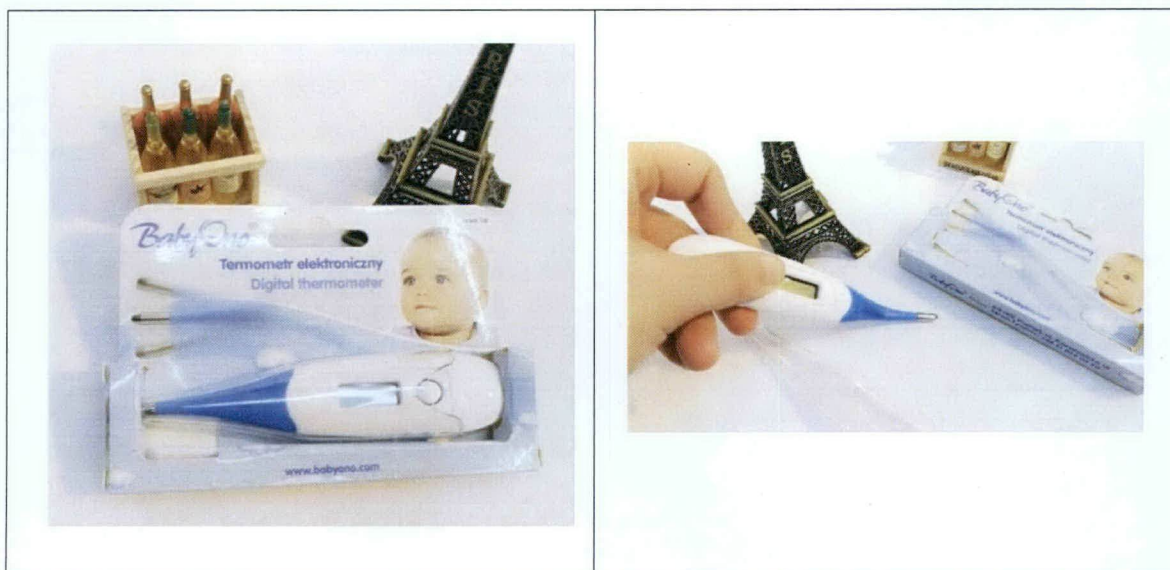
08 JAN 2019

FDA ADVISORY
No. **2019-001**

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: PUBLIC HEALTH WARNING AGAINST THE PURCHASE AND USE OF UNREGISTERED MEDICAL DEVICE "BABY ONE DIGITAL THERMOMETER"

The Food and Drug Administration (FDA) hereby advises all concerned healthcare professionals, establishment and general consuming public against the purchase and use of **BABY ONE DIGITAL THERMOMETER** whose pictures appear below.



FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Pursuant to the provision of Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", **the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of any health product that is adulterated, unregistered or misbranded are prohibited.**

The abovementioned product did not undergo the evaluation process of the FDA. Thus, the agency cannot guarantee its quality and safety.




In this regard, the public is hereby advised not to purchase the above-mentioned violative product and to be vigilant against the medical device products that are not registered with FDA.

Distributors, retailers, hospitals and all healthcare professionals / users are advised to discontinue further distribution, sale and use of the said medical device product.

For more information and inquiries, please e-mail us at cdrrhrsdd@yahoo.com or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General



20181214110929