



FDA ADVISORY
No. 2017-185

28 JUN 2017

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Medical Device (Clinical Thermometer included in Playtex Baby Healthcare Kit) that are Unregistered.

The Food and Drug Administration (FDA) advises the public against the purchase and use of unregistered medical device - **Clinical Thermometer included in Playtex Baby Healthcare Kit.**



Figure 1. Playtex Baby 6pc. Healthcare Kit (Front Label)



Figure 2. Playtex Baby 6pc. Healthcare Kit (Back Label)



Post-marketing surveillance activities conducted by the FDA have verified that Playtex Baby 6pc, Healthcare Kit (see Figure 1 and 2) have not gone through the registration process of the agency and have not been issued with Certificate of Product Registration (CPR).

Pursuant to the provisions of Republic Act 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 without the proper authorization are prohibited.

Since the abovementioned products did not undergo the evaluation process of the FDA, the agency cannot guarantee their quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative products. All concerned establishments are warned not to advertise, sell or distribute the said products until such have been issued with the corresponding Certificate of Product Registration, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.


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