Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

06 MAY 2020

FDA ADVISORY
No. 2020-774

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Following Unregistered Medical Devices:**

1. **Benetech Non-Contact Infrared Thermometer**
2. **Aicare Infrared Thermometer**
3. **Sejoy Infrared Forehead Thermometer**

The Food and Drug Administration (FDA) warns the general public against the purchase and use of the following unregistered medical devices:

Figure 1. Screenshot of the unregistered "Benetech Non-Contact Infrared Thermometer" offered for sale online

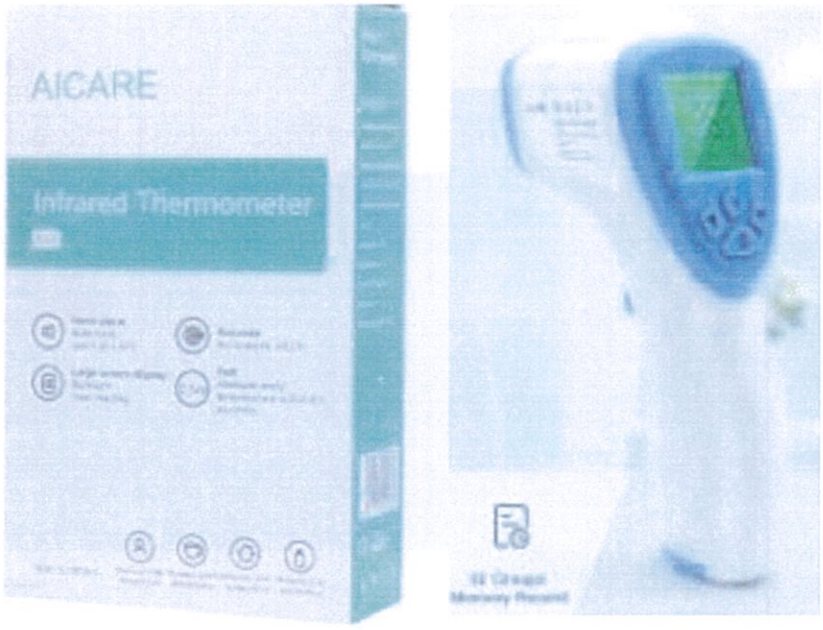

Figure 2. Screenshots of the unregistered "Aicare Infrared Thermometer" offered for sale online

Figure 3. Screenshot of the unregistered "Sejoy Infrared Forehead Thermometer" offered for sale online

The FDA verified through post-marketing surveillance that the abovementioned medical devices are not registered and the Certificate of Product Registration (CPR) has not yet been issued. Pursuant to the 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 health products without the proper authorization is prohibited.

Since these unregistered medical devices have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

In light of the foregoing, the public is advised not to purchase the violative products in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical devices until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that these products are not sold or made available in the market or in their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of these unregistered products.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport**, can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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