Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

22 JUN 2017

**FDA ADVISORY**
**No. 2017-183**

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Use of Unregistered Medical Device Products "Iodent Denture Cleanser and Iodent Denture Cleansers Overnight Whitening"

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The Food and Drug Administration (FDA) advises the public against the use of the unregistered medical device products Iodent Denture Cleanser (20 tablets) and Iodent Denture Cleansers Overnight Whitening (18 tablets):


**Figure 1. Iodent Denture Cleanser**


**Figure 2. Iodent Denture Cleansers Overnight Whitening**

Post-marketing surveillance activities conducted by the FDA have verified that the abovementioned medical device products 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 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, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

The abovementioned products 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 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 Gocvernemnt 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 Development Division - Center for Device Regulation, Radiation Health and Research of the FDA at telephone no. (02) 857-1900 loc. 8301.

Dissemination of the information to all concerned is requested.

**NELA CHARADE G. PUNO, R.Ph**
Director General

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