



22 MAR 2018

**FDA ADVISORY**  
No. **2018-100**

**TO :** **ALL HEALTH CARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT :** **Public Health Warning Against the Purchase and Use of Unregistered Medical Device SURE-GEL (Acidulated Phosphated Fluoride)**

The Food and Drug Administration (FDA) hereby advises the public against the purchase and use of the product SURE-GEL (Acidulated Phosphated Fluoride) whose particular/details are provided below:

Name of Product	Name of Manufacturer/Importer and Distributor	Status of Registration
SURE-GEL (Acidulated Phosphated Fluoride)	Not indicated	Unregistered



FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device products have not gone through the registration process of the agency and have not been issued the proper authorization in the form of Certificate of Product Registration. Pursuant to 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 from FDA is prohibited.

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

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold in any market.

For more information and inquiries, please email us at [cdrrhr\\_prsdd@fda.gov.ph](mailto: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, RPh**  
FDA Director General



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