Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2020-157-A

09 DEC 2020

TO: **THE CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Termination of the Voluntary Recall of Unisepta® Foam 2 Medical Device Disinfectant 750ml as Stated in the FDA Advisory No. 2020-157**

This is to inform the public and concerned healthcare professionals that the Voluntary recall order issued on specific lots of Unisepta® Foam 2 Medical Device Disinfectant 750ml as shown in the table below is hereby terminated by the Food and Drug Administration (FDA).

Product Name	Lot Number
Unisepta® Foam 2 Medical Device Disinfectant 750ml	A08702S
	A21511S
	A31010S
	B10630S

As stated in the FDA Advisory No. 2020-157 dated 13 February 2020, Dental Domain has conducted the voluntary recall of the aforementioned product due to the announcement from their supplier, USF Healthcare. According to their supplier, a contamination with gram negative bacteria found in water has been identified in the manufacturing process of the affected products at their subcontractor. The bacteria pose little medical risk to healthy people. However, immunocompromised patients are at higher risk of infection. They have moved to test their products to ensure the safety and decontamination of the manufacturing facilities has been done.

After due and thorough evaluation of the submitted documents by Dental Domain, FDA has determined that reasonable efforts have been made to recall and properly destroy the affected product lots in accordance with FDA Circular No. 2016-012, known as the Guidelines on Product Recall.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be subsequent findings of any violation of existing FDA laws, rules and regulations.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to monitor and seize the cited product lots if still found available in the market.

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

Dissemination of this advisory to all concerned is hereby requested

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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