

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2021-1153

2 1 MAY 2021

TO:

THE GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of Counterfeit Cosmetic Product "INFINITUS PHYTOCARE

TOOTHPASTE"

The Food and Drug Administration (FDA) warns the public from purchasing and using the below counterfeit cosmetic product:

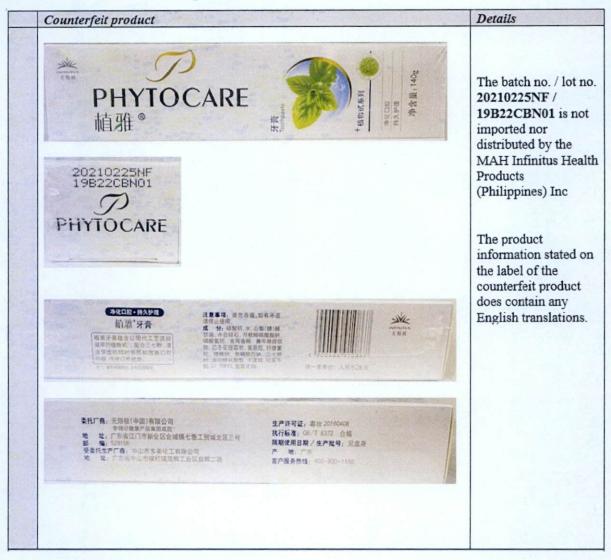


Figure 1. Counterfeit Infinitus Phytocare Toothpaste



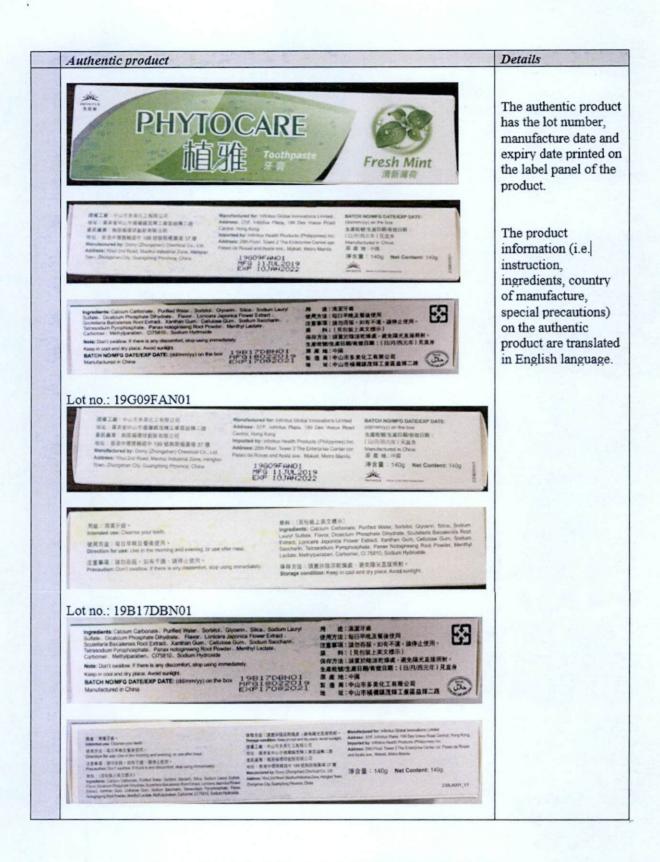


Figure 2. Authentic Infinitus Phytocare Toothpaste

The FDA has coordinated with the Market Authorization Holder (MAH), INFINITUS HEALTH PRODUCTS (PHILIPPINES) INC., and has verified that the aforementioned cosmetic product is COUNTERFEIT. According to the company INFINITUS HEALTH PRODUCTS (PHILIPPINES) INC., they are not responsible for the importation nor distribution of the aforementioned cosmetic product.

Counterfeit products did not go through the required safety assessment and the FDA verification process. These products pose potential health hazards to the consuming public since their safety and purity cannot be guaranteed. Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or restricted ingredients that in excessive amount as per ASEAN Cosmetic Directive (ACD). The use of substandard and possibly adulterated cosmetic products may result to adverse reactions, including but not limited to, skin irritation, itchiness, anaphylactic shock, and organ failure.

In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website (ww2.fda.gov.ph) has a Search feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute counterfeit cosmetic products.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with Law Enforcement Agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

Kindly contact the FDA Center for Cosmetics Regulation and Research through e-mail at cerr@fda.gov.ph or call (02) 857-1900 local 8113 or 8107.

To report any sale or distribution of unnotified cosmetic products, the online reporting facility, eReport can be accessed at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20200529152421