



FDA ADVISORY


No. 2021-2691

02 NOV 2021

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Non-Compliant Cosmetic Product " AMIRA BIO-NATURALS OATMEAL, MILK & HONEY SOAP "

The Food and Drug Administration (FDA) warns the general public from purchasing and using the non-compliant cosmetic product **AMIRA BIO-NATURALS OATMEAL, MILK & HONEY SOAP** with details specified below:

PRODUCT DETAILS	PRODUCT IMAGE/S
<p>Local Company Responsible for Placing the Product in the Market: AMIRA PHARMA INC.</p> <p>Address: 38-6 Challenger Street, Carmenville Subdivision, Cutcut, Angeles, Pampanga</p> <p>Country of Manufacture: Philippines</p> <p>Lot/Batch Number: AO11911017A</p> <p>Manufacturing Date: 11/2019</p> <p>Expiration Date: Not Indicated</p>	
<p>NON-COMPLIANCE/S</p>	
<p>The ingredients listed on the label are inconsistent with the information declared in the acknowledged product notification.</p>	

The Food and Drug Administration has verified that the abovementioned product is **NON-COMPLIANT** through its postmarketing surveillance (PMS) pursuant to Book I, Article II, Section 2 of the Rules and Regulations Implementing Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009" which provides for the relevant functions, powers and duties of the agency, including the conduct of PMS activities in the monitoring of health products.

Based on the Certificate of Product Notification issued to the company, any subsequent changes to the information previously submitted to the FDA will render the notification invalid.



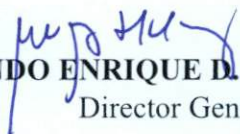
In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Always check if a product is notified with the FDA by using the FDA Verification Portal feature accessible at <https://verification.fda.gov.ph>, which may be used by typing in the name of the product before the purchase and/or using the cosmetic products.

All concerned establishments are warned not to distribute violative cosmetic product until they have fully complied with the rules and regulation of the FDA.

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 their jurisdiction.

To report any sale, distribution, complaint and/or adverse event on the use of the violative cosmetic product, the online reporting facility, **eReport** can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20211027141801