



FDA ADVISORY
No. **2019-353**

09 OCT 2019

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the following Unnotified Cosmetic Products:

1. **WILD EARTH™ SIGNATURE POTIONS BY SHABIA WALIA NATURAL BROWN HENNA**
2. **DEXE® HAIR COLOR SPRAY BLUE**
3. **DEXE® HAIR COLOR SPRAY ORANGE**
4. **DEXE® HAIR COLOR SPRAY COFFEE**
5. **EPSA® PRO-HAIR KERATIN CHOCOLATE HAIR THERAPY TREATMENT**

The Food and Drug Administration (FDA) warns the public from purchasing and using the following unnotified cosmetic products:



Figure 1. Unnotified Wild Earth™ Signature Potions by Shabia Walia Natural Brown Henna





Figure 2. Unnotified Dexe® Hair Color Spray Blue



Figure 3. Unnotified Dexe® Hair Color Spray Orange



Figure 4. Unnotified Dexe® Hair Color Spray Coffee



Figure 5. Unnotified EPSA® Pro-Hair Keratin Chocolate Hair Therapy Treatment

The FDA verified through post-marketing surveillance (PMS) that the abovementioned cosmetic products are not authorized and the Certificates of Product Notification have not been issued. 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.

Since these unnotified cosmetic products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The use of such violative products may pose health risks to consumers.

Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product as listed in the Annex II, Part I of the ASEAN Cosmetic Directive (ACD), such as heavy metals like Lead (Pb) and from hair-smoothing products containing formaldehyde. Formaldehyde have been associated with reactions such as eye problems, nervous system problems (headaches, and dizziness), respiratory tract problems, nausea, chest pain, vomiting and rash. Skin sensitivity can develop after repeated contact with formaldehyde-related ingredients. Lead (Pb) exposure may cause anaemia, hypertension, renal impairment, immunotoxicity and toxicity to the reproductive organs.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website (www.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 violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

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 ccrr@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 www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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