Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

01 April 2013

FDA Advisory
No. 2013-005

SUBJECT: PUBLIC HEALTH WARNING ON TEMPORARY SKIN-STAINING COSMETIC PRODUCTS

Last month, the USFDA warned the public that it has received several reports on adverse skin reactions produced by some temporary skin-staining cosmetic products. As young as a five-year-old boy developed severe reddening or inflammation of the skin where the temporary tattoo was placed.

All temporary skin-staining products, commonly known as henna dye products, need Philippine FDA approval as cosmetic products before they are marketed or used in the country. It is important that tattoo dye preparations are approved by the FDA. First, all ingredients used in the preparations are disclosed by the manufacturers, importers, traders or distributorsand evaluated by the FDA if they are approved for cosmetic use. It is the extra ingredients that are potentially harmful, especially if these are from coal-tar hair dye containing p-phenylenediamine (PPD). In some people, PPD evokes skin reactions which may lead to severe inflammation and scar formation.There is no way of telling if PPD is mixed in henna preparations unless they are properly labeled according to the Philippine FDA standard. Second, consumers are assured that the temporary skin-staining products are manufactured under current Good Manufacturing Practice (cGMP) as prescribed in the ASEAN Cosmetic Directive (ACD). Third, the consumers would be able to identify and report the specific cosmetic product that caused the adverse reaction to FDA.

Consumers are advised to ask for FDA market authorization or cosmetic notification before receiving a temporary tattoo. Consumers who experienced adverse reactions are requested to send their report at info@fda.gov.ph.

So far, the Philippine FDA has not yet received any consumer complaint, but unlicensed temporary tattoo dye manufacturers, importers, traders or distributorsare strongly advised to apply for a license to operate and market authorizationfrom the FDA. Failure to do so is a direct violation of Republic Act No. 3720 (as amended), otherwise known as the Food, Drugs and Devices, and Cosmetic Act and Republic Act No. 9711, otherwise known as the FDA Act of 2009.

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