



14 January 2014

**FDA ADVISORY**

No. ~~2014~~ 005

**SUBJECT: Consumers Warning Against Buying Unregistered ONAMI Slimming Underwear Products that have Unsubstantiated and Baseless Claims that it Can Detoxify the Body and Burn Fats, among other Therapeutic Claims**



wear (Black)

The Food and Drug Administration (FDA) has monitored a slimming underwear product, with a brand name ONAMI, being advertised in prints and online with the following claims: a) to detoxify and burn fats, b) strengthen the immune system, c) boost metabolism, d) increase mental alertness, e) reduction of fatigue and stress, f) reduction of aches and pains, and g) prevention of body odors without any clinical or scientific studies to back the therapeutic claims. Upon further investigation, the product is not registered with the FDA.

The FDA regulates all devices that have therapeutic or health claims. Manufacturers or distributors of such devices need to secure License to Operate (LTO) as manufacturer or distributor with the FDA. These products need to be registered also with the FDA to ensure that they meet safety, efficacy and quality standards, and all health claims made are truthful and are not misleading. Only health products that meet the FDA standards are issued the Certificate of Product Registration (CPR). Only health products that are FDA-registered may be offered for sale or use and advertised, among other promotional and marketing activities.

The FDA has yet to receive a CPR application with the required submission of clinical reports or studies to substantiate any therapeutic or health claim from the manufacturer or distributor in the country.

Peddlers and advertisers claim that “tourmaline”, a semi-precious gemstone also known as “Electric Stone”, can “deliver a number of health benefits”. They also claim that the “black tourmaline” embedded in the underwear “generates a weak electric current when heated or applied the right amount of pressure”. They also claim that tourmaline produces “far infrared rays” and “converts moisture in the air to negative ions”.

All consumers are hereby warned against buying the said unregistered product from the market or through online.

Manufacturers or distributors of the product in the Philippines are strongly advised to remove the said products in the market and apply for an LTO and the CPR before







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offering them for sale or use. Likewise, all mall owners and outlets carrying the ONAMI slimming underwear are requested to remove them from shelves and racks.

All field Food and Drug Regulation Officers are hereby ordered to confiscate and seize all ONAMI underwear slimming products from the market and conduct investigation on the manufacturer or distributor in the country.

For more information and clarification regarding this matter, please email us via [info@fda.gov.ph](mailto:info@fda.gov.ph) or call the Center for Devices, Radiation Regulation and Health Research (CDRRHR) at 711-6016 or 711-6824. For any complaints of adverse reactions or to report unregistered health products in the market, kindly email us via [report@fda.gov.ph](mailto:report@fda.gov.ph).

  
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