



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



12 August 2014

FDA Advisory
No. **2014-064**

**SUBJECT: PUBLIC HEALTH WARNING AGAINST THE USE OF
UNREGISTERED PRODUCT LEISURE BURN BODY FAT
ORANGE JUICE**



The public is hereby warned by the Food and Drug Administration (FDA) against the use of unregistered Leisure Burn Body Fat Orange Juice manufactured by America Huarui Sheng Pharmaceutical Co., Ltd.

Field Regulatory Inspectors from Department of Health – Center for Health Development – Tuguegarao City, Cagayan Valley collected samples of Leisure Burn Body Fat Orange Juice products as part of the Post-Marketing

Surveillance.

This product is not registered in the Philippines, and FDA has determined that the product contains Amphetamine and Sibutramine, which are not stated in its label.

Sale and distribution of Leisure Burn Body Fat Orange Juice violate R.A. 9711 s. 2009 or the Food and Drug Administration Act of 2009 which provides that “the manufacture, importation, exportation, transfer or distribution of any food, cosmetics, household hazardous substances or urban pesticides without the appropriate authorization from the FDA is prohibited” and R.A. 3720 s. 1987 (an act to ensure the safety and purity of foods, drugs, and cosmetics being made available to the public by creating the Food and Drug Administration which shall administer and enforce the laws pertaining thereto, and which provides that “a food shall be deemed to be misbranded if its labeling is false or misleading in any particular”).

The FDA has suspended the manufacture, importation, distribution, or marketing of all Sibutramine products (single component and Sibutramine-containing products) due to unnecessary cardiovascular risks to patients, as per FDA Memorandum Circular No. 2010-019.

Amphetamine is a dangerous drug and its sale, trading, administration, dispensation, delivery, distribution and transportation is an unlawful act, pursuant to R.A. No. 9165 s. 2002 known as the Comprehensive Dangerous Drugs Act of 2002.



As stated in its label, Leisure Burn Body Fat Orange Juice has the following claims: "has the using improvement for gastrointestinal function. This product is mainly for all the obese or fat can decrease redundant and excessive verrcula, burning and promoting redundant fat and adipose, promote body fat metabolism, regulate endocrine system".

Distributors, retailers, hospitals, pharmacies, or clinics are instructed to discontinue further distribution, sale and use of the unregistered Leisure Burn Body Fat Orange Juice.

The field Food and Drug Regulation Officers are ordered to confiscate all unregistered food supplements, particularly Leisure Burn Body Fat Orange Juice in the market or from individuals offering this product for sale.

All local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

To check if a product is registered with the FDA, please log in at www.fda.gov.ph and type in the name of the product in the search bar. To report any unregistered health product, please email us at report@fda.gov.ph. Consumers may also email the FDA at info@fda.gov.ph for any question or additional information.

Any adverse reaction experienced from use of the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab and proceed to fill-out all of the required fields.


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