Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 June 2015

FDA Advisory No. 2015-038

SUBJECT: VOLUNTARY PRODUCT RECALL OF SPECIFIC LOTS OF SINOMAN WITH GREEN TEA

This is to inform the public that Diamond Laboratories, Inc. is voluntarily recalling the impacted lots of Sinoman with Green Tea containing the following: *Camellia sinensis (*Tea), *Crataegus pinnatifida* (Bunut), *Prunella vulgaris* (Pakuan), *Phaseolus angularis* (Patani), *Pogostemon cablin* (Kablin), *Poria cocos wolf* (Kabute), *Citrus chachinensis hortorum* (Dalandan), *Fructus hordei germinatus* (Boyag/Kabuyao-aso), *Massa medicata fermentata* (Dalupang/Kuakuakohan), *Cassia tora* (Balatong-aso), *Pharbitis nil* (Kamokamotihan), *Rhizoma alismatis* (Gauai-gauai/Tikog), *Raphanus sativus* (Labanos) 1.5 g/0.27 g/0.24 g/0.12 g/0.12 g/0.12 g/0.105 g/0.105 g/0.105 g/0.09 g/0.09 g/0.075 g/0.06 g due to unauthorized repackaging of the product when the establishment does not have a valid License to Operate (LTO) as a Repacker.

The details of the affected lots are as follows:

REGISTRATION NUMBER	**HDL-33**
LOT NUMBER/ EXPIRY DATE	**18400R/January 2016** **18400R2/August 2015** **18400R3/August 2015**
MANUFACTURER	**WEI HUI TRADING – HONGKONG**
IMPORTER/DISTRIBUTOR	**DIAMOND LABORATORIES, INC. – #8 FERIA ROAD, COMMONWEALTH AVENUE, DILIMAN, QUEZON CITY**

Sinoman with Green Tea is an antioxidant combination which prevents possible degenerative disease. The product is approved to be packed into cans of 20 individual tea bags or boxes of 20's and 60's sachet.

The affected product lots present safety risks and potential adverse health consequences. Therefore, distributors, retailers, or pharmacies that have the affected lots of Sinoman with Green Tea are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

All Field Regulatory Operations Officers (FROOs) are ordered to monitor the availability of the product lots in the market, appropriately seal discovered stocks of the affected lots of the product, and instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Consumers may contact Diamond Laboratories, Inc. at telephone number +632 932-7555 loc. 129 or 140 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

Any suspected adverse reaction experienced from the use of the aforementioned product lots should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150525144541

[1]Pursuant to DPO 2015-1845