Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 NOV 2015

FDA ADVISORY
No. 2015-088

SUBJECT: Termination of Product Recall Order Issued on Specific Lots of Sinoman with Green Tea

This is to inform the public that the Product Recall Order (PRO) issued on affected lots (18400R, 18400R2 & 18400R3) of Sinoman with Green Tea containing *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 is hereby terminated by the Food and Drug Administration (FDA). This product with registration number HDL-33 was manufactured by Wei Hui Trading in Hongkong and imported by Diamond Laboratories, Inc.

As stated in the FDA Advisory No. 2015-038 dated 15 June 2015, FDA informed the public of the voluntary recall of the above-mentioned affected lots of Sinoman with Green Tea due to unauthorized repackaging of the product when the Marketing Authorization Holder (MAH), Diamond Laboratories, Inc., does not have a valid License to Operate (LTO) as a Repacker.

After due and thorough evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the MAH to recall and properly destroy the impacted product lots in accordance with Bureau Circular No. 8, s. 2001, known as the Guidelines to be Observed on the Implementation of the Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor and seal discovered stocks of the affected lots of the subject product. Please instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding this recalled product.

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Secretary of Health
Acting Director General[1]

DTN: 20151023155047
[1]Pursuant to DPO 2015-1845