Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-096

22 AUG 2016

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Reiteration of Public Health Warning Against the Use of the Unregistered Ginseng Lin-Zi Gejie Pil Capsule.**

The Food and Drug Administration (FDA) advises the public against the use of the following unregistered drug product:

Ginseng Lin-Zi Gejie Pil Capsule
Tiensin Drug Manufactory – Tientsin, China

Figure 1. Unregistered Drug Product

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug product. This poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

The FDA recent laboratory analysis showed that the product contains **Dexamethasone.** It must be noted that **Dexamethasone** is a steroid, classified as prescription drug. The misuse and/or chronic use of steroids like **Dexamethasone** may result to serious adverse reactions such as:

- gastrointestinal bleeding and ulcers
- osteoporosis
- muscle weakness
- obesity
- dyslipidemia
- increase risk for infections
- poor wound healing
- if stopped abruptly, could cause withdrawal signs and symptoms such as hypotension, shock and coma.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified product. Anyone found selling the said products will be penalized.

Likewise, 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.

Consumers are advised to purchase their medications only from FDA-licensed establishments. In addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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