Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 May 2015

FDA ADVISORY
No2015 -026

SUBJECT: **Public Health Warning Against the Use of the Following Unregistered Drug Products:**

1. **Glutatione (Tationil) 600 mg/ 4 mL polvere e solvente per soluzione iniettabile I.M./ E.V.**
2. **L-Carnitina (Lefcar) 1 g/ 5 mL soluzione iniettabile**
3. **Ascorbic Acid (Vitamin C Injection) 500 mg/ 2 mL Ampoule for Intramuscular or Intravenous Injection, Manufactured by T.P. Drug Laboratories (1969) Co., Ltd.**
4. **Triamcinolone Acetonide (Kanolone) 10 mg/ mL Injection**

The Food and Drug Administration advises the public against the use of the following unregistered drug products:

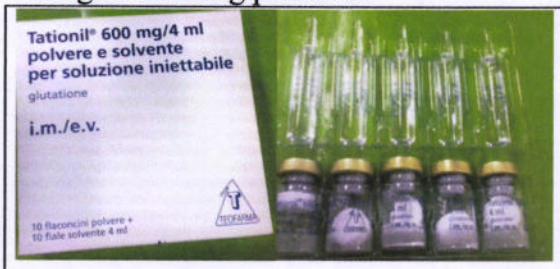
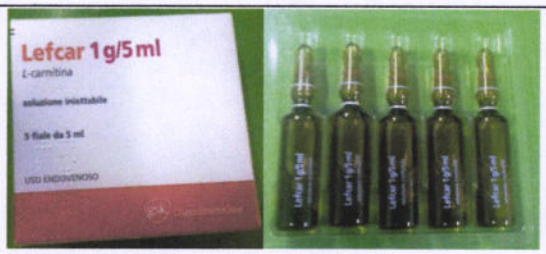
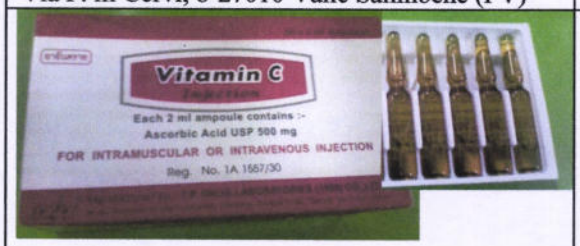
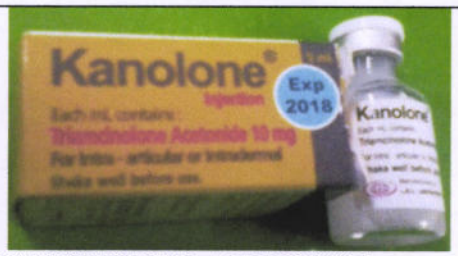
 **GLUTATIONE (TATIONIL) 600 mg/ 4 mL POLVERE E SOLVENTE PER SOLUZIONE INIETTABILE I.M./ E.V.** Marketing Authorization Holder: Teofarma s.r.l. – Via F. lli Cervi, 8-27010 Valle Salimbene (PV)	 **L-CARNITINA (LEFCAR) 1 g/ 5 mL SOLUZIONE INIETTABILE** Marketing Authorization Holder: GlaxoSmithKline S.p.A. – Via Fleming, 2-Verona
 **ASCORBIC ACID (VITAMIN C INJECTION) 500 mg/ 2 mL AMPOULE FOR INTRAMUSCULAR OR INTRAVENOUS INJECTION** Manufactured by T.P. Drug Laboratories (1969) Co., Ltd. – 98 Soi Sukhumvit 62, Yak 1, Bangchak, Parakanong, Bangkok 10260, Thailand	 **TRIAMCINOLONE ACETONIDE (KANOLONE) 10 mg/ mL INJECTION** Manufactured by L.B.S. Laboratory Ltd., Part. – 602 Soi Panichanat, Sukhumvit 71 Rd., Bangkok 10110,Thailand

Table 1.Unregistered Drug Products

The abovementioned drug products pose 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.

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In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the field Food and Drug Regulation Officers of this Office are hereby ordered to seize the aforementioned unregistered drug products found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified products. 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.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that 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. Moreover, please 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 email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), please email us via adr@fda.gov.ph.

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Acting Director General[1]

DTN:20150422142254

[1] Pursuant to DPO 2015-1845