Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201958

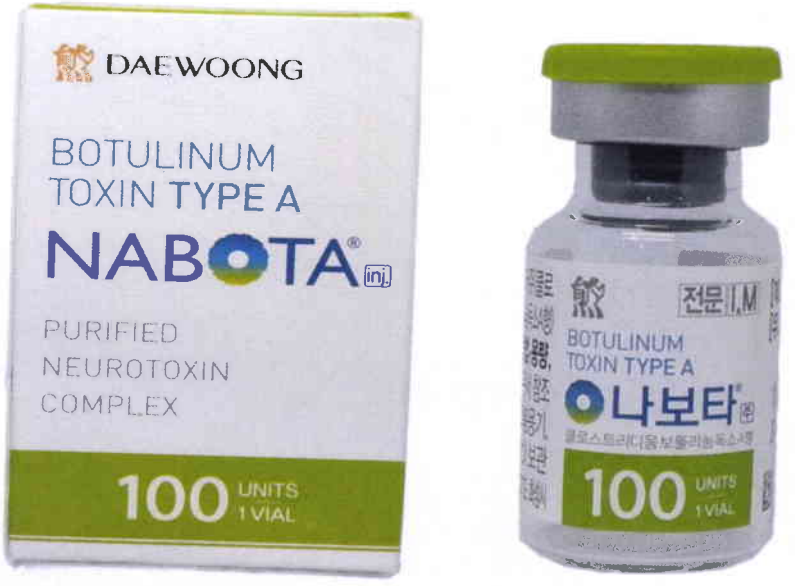
28 OCT 2020

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

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

1. **Botulinum Toxin Type A 100 Units/1Vial (Primary Packaging) Daewoong Botulinum Toxin Type A Nabota® Inj. Purified Neurotoxin Complex 100 Units/1 Vial (Secondary Packaging)**
2. **Lidocaine Carbonate Injection 5ml:86mg**
3. **Levocarnitine For Injection 1.0 g (Sample no.1)**
4. **Triamcinolone Acetonide Acetate Injection 5ml:50mg (Sample no.2)**
5. **[Label in foreign language] 0.3ml 1ml: 5mg ampoule (Sample no.3)**

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



Botulinum Toxin Type A 100 Units/1Vial (Primary Packaging) Daewoong Botulinum Toxin Type A Nabota® Inj. Purified Neurotoxin Complex 100 Units/1 Vial (Secondary Packaging)

Figure 1. Unregistered drug product

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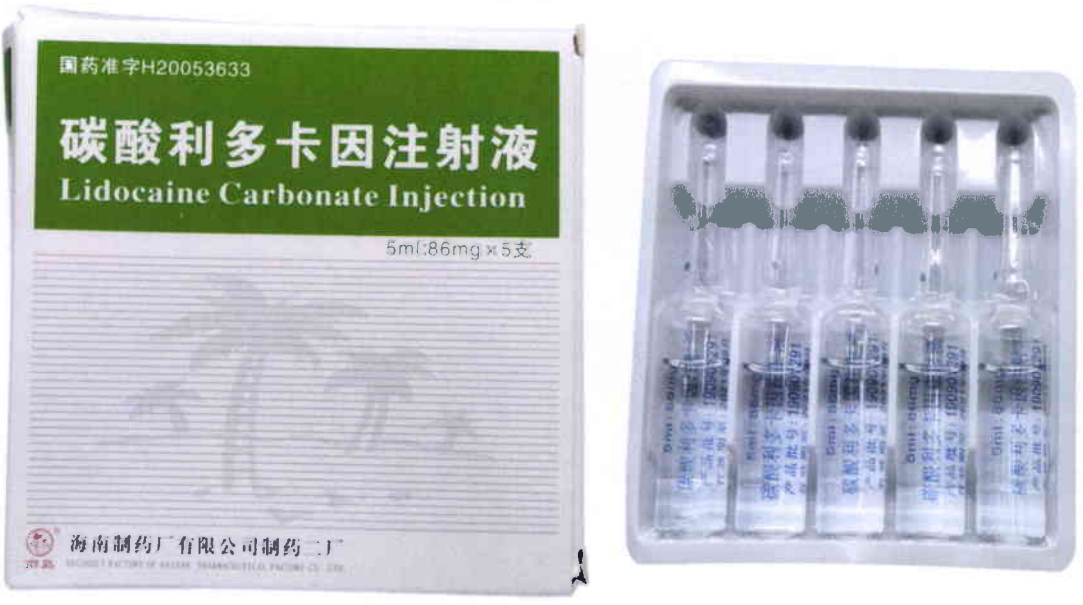
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph

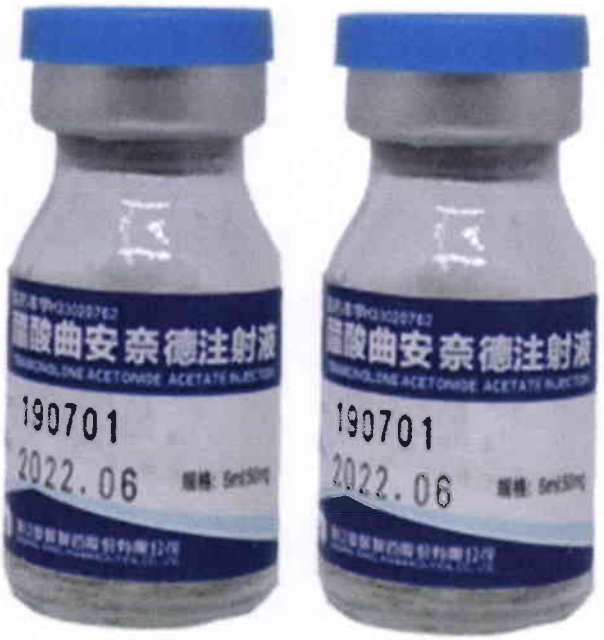


Lidocaine Carbonate Injection 5ml:86mg
by: Secondly Factory of Hainan Pharmaceutical Factory Co., Ltd.

Figure 2. Unregistered drug product

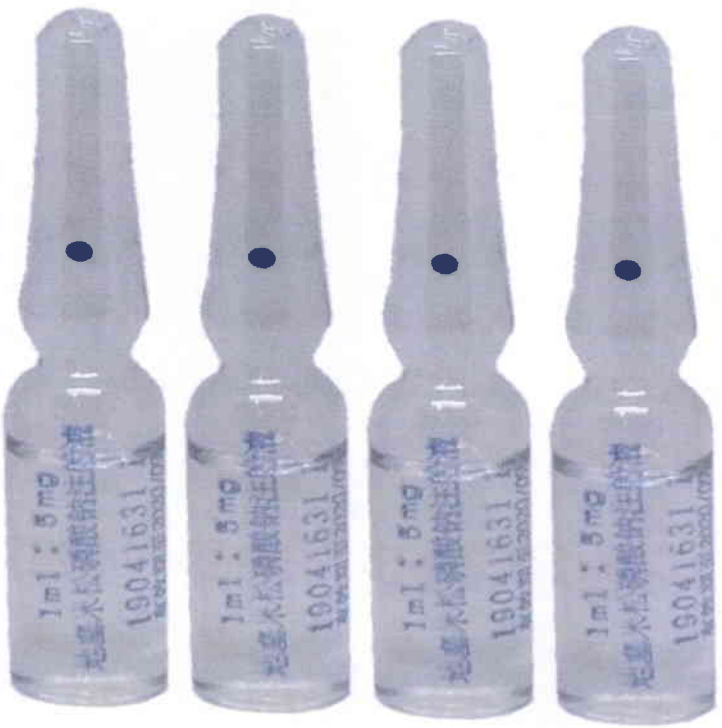
Levocarnitine For Injection 1.0 g (Sample no.1)

Figure 3. Unregistered drug product



Triamcinolone Acetonide Acetate Injection 5ml:50mg (Sample no.2)
by Zhejiang Xianju Pharmaceutical Co., Ltd.

Figure 4. Unregistered drug product



[Label in foreign language] 0.3ml 1ml: 5mg ampoule (Sample no.3)

Figure 5. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

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 **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20201020122413