Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 2020-1956

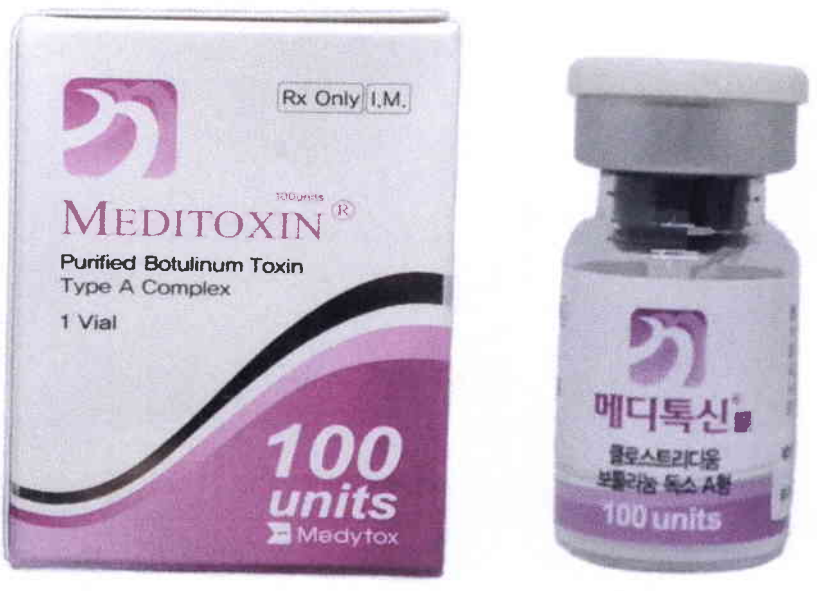
28 OCT 2020

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

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

1. **Meditoxin® Purified Botulinum Toxin Type A Complex 100 units Medytox**
2. **Aminogen-X Injection 250 mL I.M.**
3. **Acnezon® 0.07 fl.oz/2ml**
4. **Bisotin Inj. "N.K." 2ml (Primary packaging) Bisotin "N.K."2ml x 50A (Secondary packaging)**
5. **Botulinum Toxin Type A 200 Units/1 Vial (Primary Packaging) Daewoong Botulinum Toxin Type A Nabota® Inj. Purified Neurotoxin Complex Units/1 Vial (Secondary Packaging)**

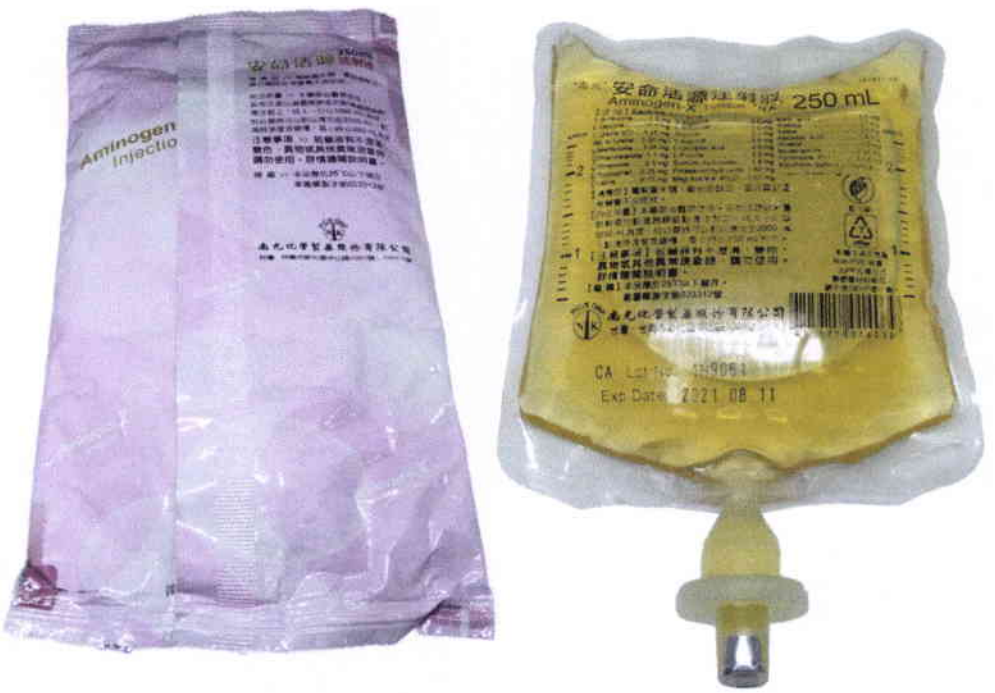
The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



Meditoxin® Purified Botulinum Toxin Type A Complex 100 units Medytox

Figure 1. Unregistered drug product

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph



Aminogen-X Injection 250 mL I.M.

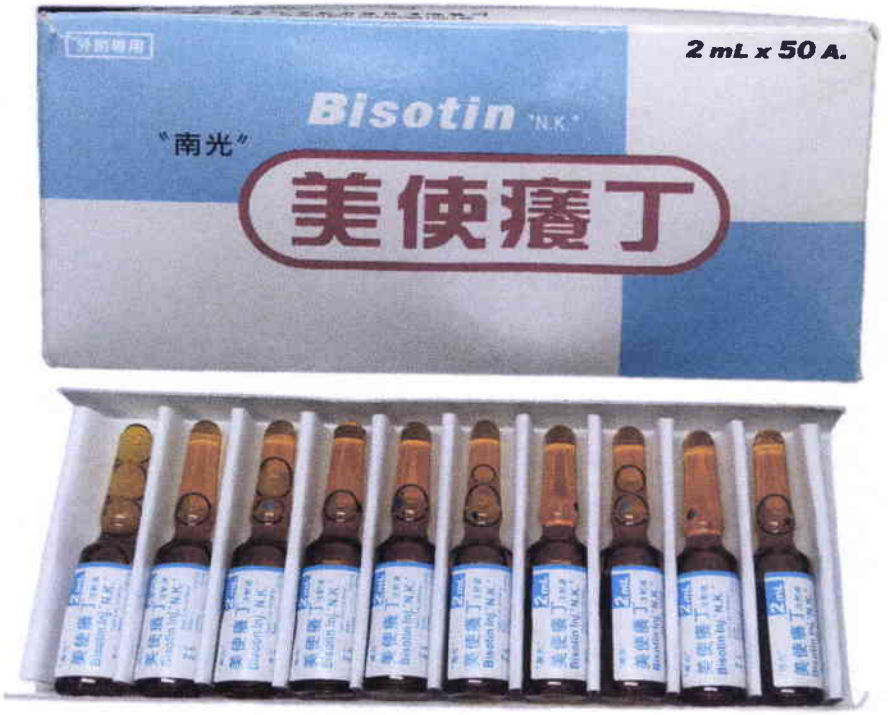
Figure 2. Unregistered drug product

Acnezon® 0.07 fl.oz/2ml

Distributor Wholesaler : Dermica Laboratories, Europe, S.I - Avenida Ciclista Mariano Rojas, piso 1°, 3009, Murcia Spain

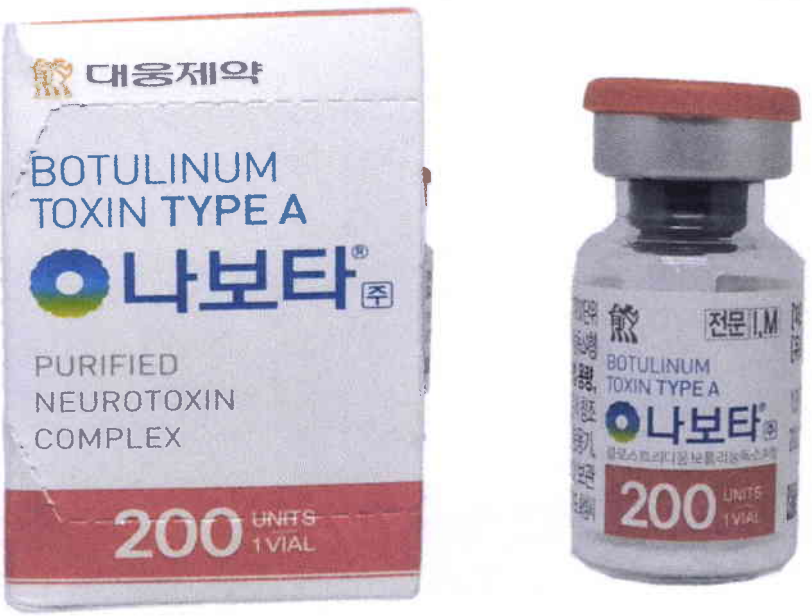
by: Dermica Laboratories, AD-Reitergasse n°1 2nd Floor, 8004, Zurich, Switzerland

Figure 3. Unregistered drug product



Bisotin Inj. "N.K." 2ml (Primary packaging)
Bisotin "N.K."2ml x 50A (Secondary packaging)

Figure 4. Unregistered drug product



Botulinum Toxin Type A 200 Units/1 Vial (Primary Packaging)
Daewoong Botulinum Toxin Type A Nabota® Inj. Purified Neurotoxin Complex Units/1 Vial (Secondary Packaging)

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: 20201016220129