Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 2016-140

16 NOV 2016

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

SUBJECT: **Public Health Warning Against the Use of the Counterfeit Albumin (Human) U.S.P. Human Albumin Grifols 25% Solution "Manufactured by Instituto Grifols, S.A., Barcelona, Spain"**

The Food and Drug Administration (FDA) advises the public against the use of the counterfeit Albumin (Human) U.S.P. Human Albumin Grifols 25% Solution "Manufactured by Instituto Grifols, S.A., Barcelona, Spain".

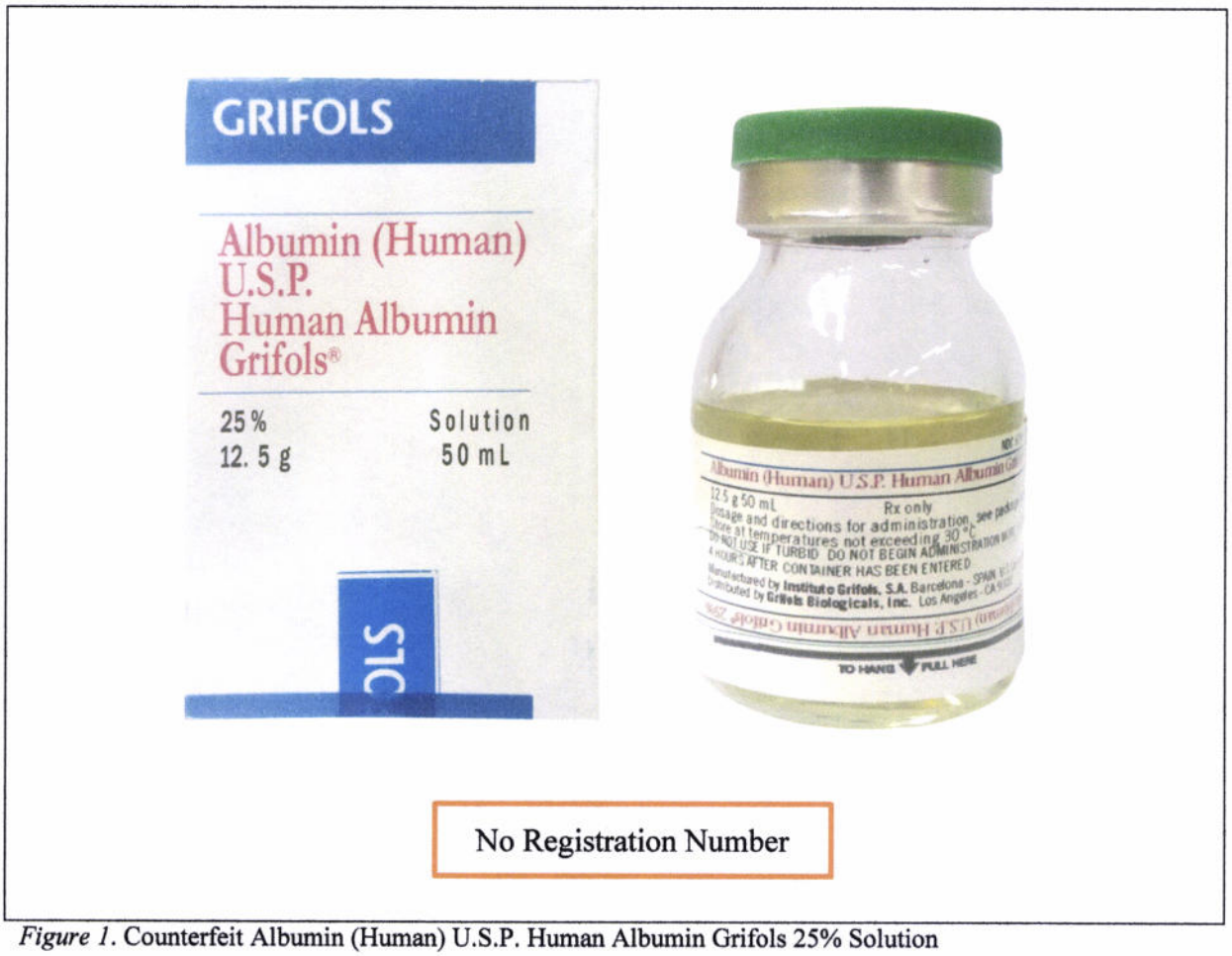

Figure 1. Counterfeit Albumin (Human) U.S.P. Human Albumin Grifols 25% Solution

The above-mentioned product imitates the one being commercialized in the U.S.A. This was confirmed by GB Distributors, Inc., the Marketing Authorization Holder (Importer) of the registered product being distributed in the Philippines - Albumin (Human) 25%, USP (Plasbumin-25) 50 mL Single Dose Vial.

Figure 2. Authentic Albumin (Human) 25%, USP (Plasbumin-25) 50 mL Single Dose Vial with FDA Registration No.: BR-76, Manufactured by Grifols Therapeutics, Inc. USA, Imported and Distributed by GB Distributors, Inc. – Cupang, Muntinlupa City

All healthcare professionals and the general public are hereby warned to be vigilant of the counterfeit drug product presented in Figure 1. This product 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, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs.

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 drug product. Anyone found selling the said drug product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this drug product is 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 e-mail us at info@fda.gov.ph. To report continuous sale or distribution of counterfeit drug 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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Director General

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