



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



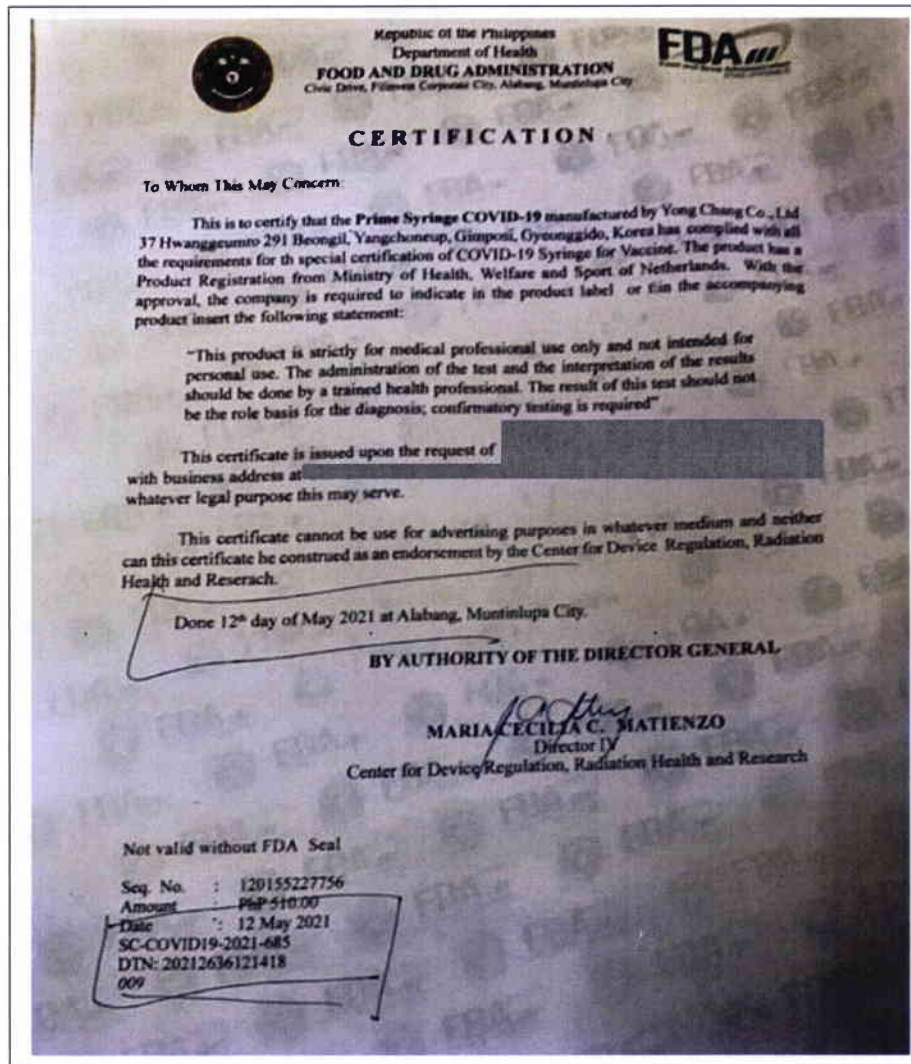
01 JUN 2021

FDA ADVISORY
No. **2021-1174**

TO: ALL CONCERNED HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Fake Special Certification for Prime Syringe COVID-19 and the Unregistered Medical Device Product "PRIME SYRINGE COVID-19"

The Food and Drug Administration (FDA) warns all concerned healthcare professionals and the general public against the fake Special Certification for Prime Syringe COVID-19 (See image below).



The FDA verified that the abovementioned Special Certification is a fake/falsified document. Special Certification is being issued by the FDA for COVID-19 test kits and not for syringes. Pursuant to Section 11(e) of Republic Act (RA) No. 3720 otherwise known as "Food, Drug, and Cosmetic Act" as amended by RA 9711 or the "Food and Drug Administration Act of 2009" which states that "Forging, counterfeiting, simulating or falsely representing or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Act" is a prohibited act.

Furthermore, FDA warns all concerned that the medical device, Prime Syringe COVID-19, identified in the fake Special Certification is unregistered and no corresponding product notification/registration certificate has been issued for the said product. Pursuant to the provisions of RA 9711, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

All concerned establishments are warned not to use the said fake Special Certification nor distribute, advertise, or sell the said violative medical device product until the product notification/registration certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

Always check if a product has been notified/registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Notification/Registration number on the product label in the form of either CMDN-xxx, DVR-xxxx or MDR-xxxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that the product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unnotified/unregistered product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrhr@fda.gov.ph indicating on the subject the concerned Advisory, or call (02) 8857-1900 loc. 8301.

To report any use of the above-mentioned fake Certificate or sale or distribution of unnotified/unregistered medical device, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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Director General