Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

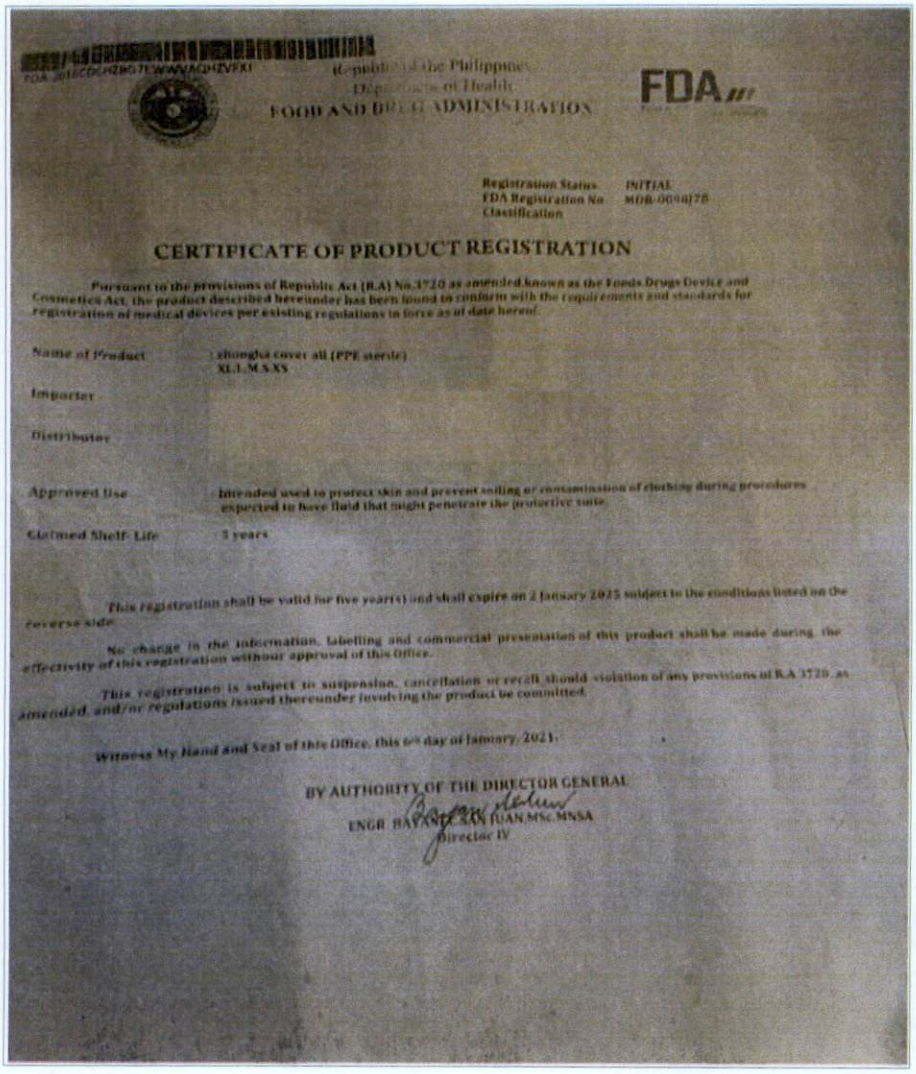
08 APR 2022

FDA ADVISORY
No. 20220875

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

SUBJECT: **Public Health Warning Against the Fake Certificate of Product Registration for Zhongka Cover All (PPE Sterile) and the Unnotified Medical Device Product "Zhongka Cover All (PPE Sterile)"**

The Food and Drug Administration (FDA) warns all concerned healthcare professionals and the general public against the fake Certificate of Product Registration for Zhongka Cover All (PPE Sterile) (See image below).



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Registration Status: INITIAL
FDA Registration No.: MDR-00[illegible]75
Classification:

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A) No.3720 as amended known as the Foods Drugs Device and Cosmetics Act, the product described hereunder has been found to conform with the requirements and standards for registration of medical devices per existing regulations in force as of date hereof.

Name of Product: zhongka cover all (PPE sterile)
XL,L,M,S,XS

Importer:

Distributor:

Approved Use: Intended used to protect skin and prevent soiling or contamination of clothing during procedures expected to have fluid that might penetrate the protective suite.

Claimed Shelf-Life: 3 years

This registration shall be valid for five year(s) and shall expire on 2 January 2025 subject to the conditions listed on the reverse side.

No change in the information, labelling and commercial presentation of this product shall be made during the effectivity of this registration without approval of this Office.

This registration is subject to suspension, cancellation or recall should violation of any provisions of R.A 3720, as amended, and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 6th day of January, 2021.

BY AUTHORITY OF THE DIRECTOR GENERAL

ENGR. BAYANI SAN JUAN, MSc, MNSA
Director IV

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The FDA verified that the abovementioned Certificate of Product Registration is a fake/falsified document. 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, Zhongka Cover All (PPE Sterile), identified in the fake Certificate of Product Registration is unnotified 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 Certificate of Product Registration 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 **cdrrhr@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, contact the online reporting facility eReport through e-mail at **ereport@fda.gov.ph.**

Dissemination of this advisory to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN 20220317153148