



24 FEB 2022

FDA ADVISORY
No. 20220410

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product "LVTA PROTECTIVE MASK DISPOSABLE 3PLY EAR-LOOP TYPE"

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unnotified medical device product:

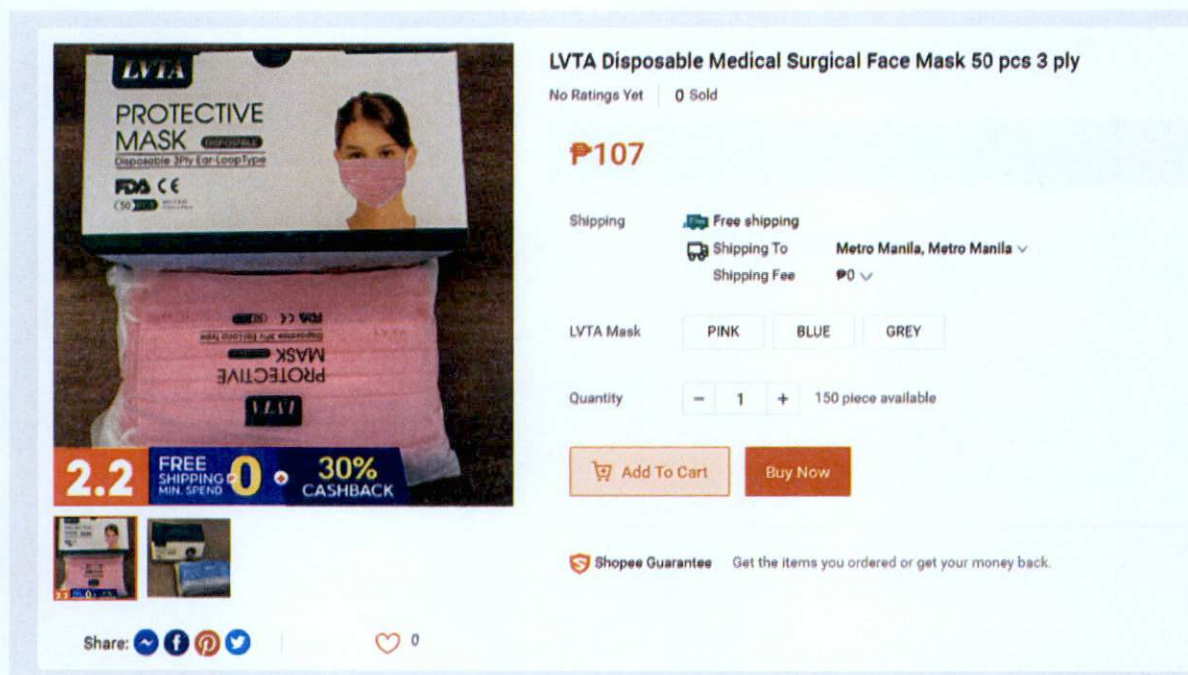


Figure 1. Unnotified LVTA Protective Mask Disposable 3Ply Ear-Loop Type advertised at Shopee.ph



LVTA Protective Mask Disposable Facemask 3ply FDA CE Medical Grade

★★★★★ 15 Ratings



Brand: No Brand | More Medical Supplies from No Brand

₱75.00

Promotions **Min. Spend ₱249.00**

color_family **Pink**



Quantity Only 5 items left

Buy Now **Add to Cart**



LVTA 3 ply Original Disposable Medical Surgical Face Mask 50 pcs

★★★★★ 12 Ratings



Brand: No Brand | More Medical Supplies from No Brand

₱199.00

Promotions **Min. spend ₱500.00**

color_family **Blue**



Quantity Only 5 items left

Buy Now **Add to Cart**

Figure 2. Unnotified LVTA Protective Mask Disposable 3Ply Ear-Loop Type advertised at Lazada.com.ph

The FDA verified through post-marketing surveillance that the above mentioned medical device product is not notified and no corresponding Product Notification Certificate has been issued. Pursuant to the 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this unnotified medical device product has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Notification Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been notified 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 number on the product label in the form of CMDN-xxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this 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 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 sale or distribution of 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

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