



FDA ADVISORY
No. **2021-1125**

21 MAY 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Products “DENTAL AMALGAMS”

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

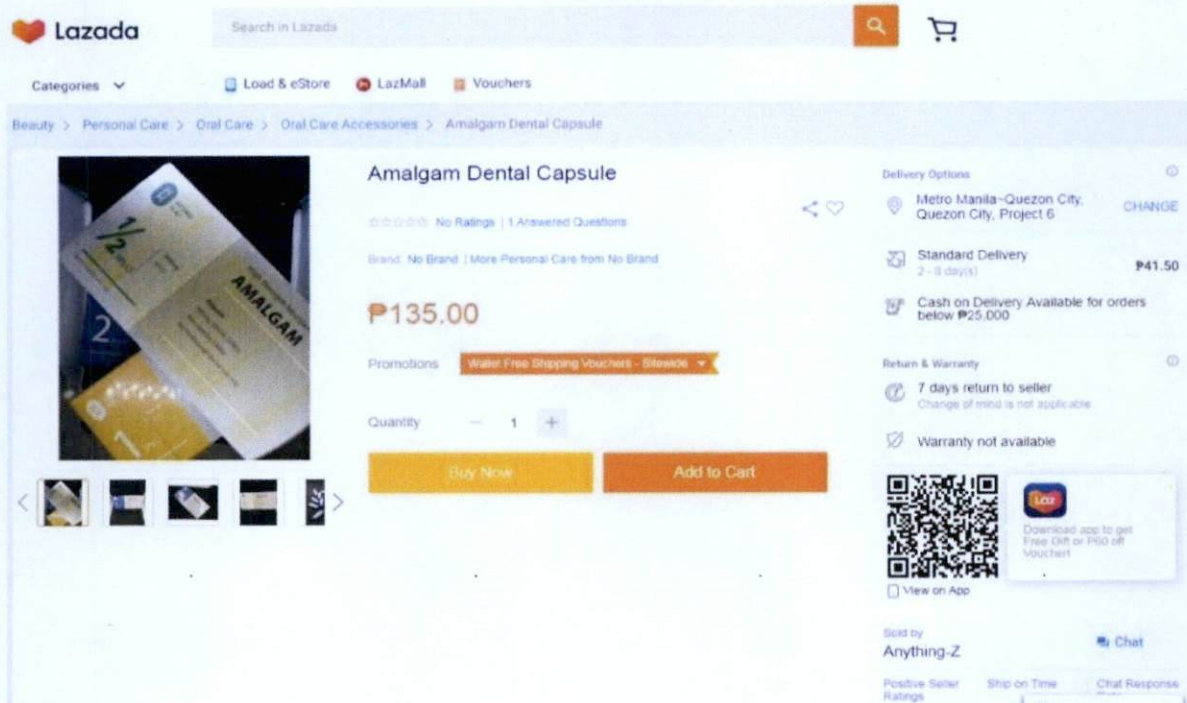








Figure 1. Unregistered Amalgam Dental Capsule


Seller Centre | Sell on Shopee | Download | Follow us on  

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 Up to 50% off on Colgate  

Dress Face Mask Wallpaper Tops Sandals Bts Face Shield Crochet


Shopee > Health & Personal Care > Medical Supplies > [DENTAL] 1 or 2 SPILL AMALGAM CAPSULE






[DENTAL] 1 or 2 SPILL AMALGAM CAPSULE


No Ratings Yet | 0 Sold

₱90 - ₱110

Shipping  Pre-Order (ships in 10 days)



 Free shipping
Free shipping with min order of ₱249


 Shipping To **Metro Manila, Metro Manila** 







Shipping Fee **₱0 - ₱40** 

1 Or 2 Spill 1 spill 2 spill

Quantity - 1 + 8 piece available



 


 **Shopee Guarantee** Get the items you ordered or get your money back.




Share:       0

5.5 FREE SHIPPING MIN. SPEND **10%** CASHBACK

Figure 2. Unregistered Dental Amalgams (1 or 2 Spill)


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 Up to 50% off on Colgate  

Dress Face Mask Wallpaper Tops Sandals Bts Face Shield Crochet


Shopee > Health & Personal Care > Medical Supplies > 2 Spill Dental Amalgam Alloy






Preferred 2 Spill Dental Amalgam Alloy

4.9  15 Ratings 223 Sold



₱50


Shipping  Free shipping
Free shipping with min order of ₱500

 Shipping To **Metro Manila, Metro Manila** 

Shipping Fee **₱0 - ₱45** 

Quantity - 1 + 0 piece available

 **Shopee Guarantee** Get the items you ordered or get your money back.












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Figure 3. Unregistered 2 Spill Dental Amalgam Alloy


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 Up to 50% off on Colgate 

Dress Face Mask Wallpaper Toys Sandals Bra Face Shield Crop top


Shopee > Health & Personal Care > Personal Care > Oral Care > Dental Amalgam 2 spills






Dental Amalgam 2 spills

No Ratings Yet 5 Sold


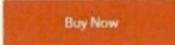
₱105


Shipping  Free shipping
Free shipping with min order of ₱500

 Shipping To **Metro Manila, Metro Manila** 

Shipping Fee **₱0 - ₱40** 

Quantity - 1 + 995 piece available

 **Shopee Guarantee** Get the items you ordered or get your money back.












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Figure 4. Unregistered Dental Amalgam 2 Spills


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 ₱1 Deals All Day on Overseas Festival! 

Dress Face Mask Sandals Toys Bra Face Shield Wallpaper Crop top


Shopee > Health & Personal Care > Personal Care > Oral Care > Dental Amalgam 1spill






Dental Amalgam 1spill

No Ratings Yet 0 Sold

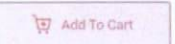
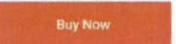
₱85

Shipping  Free shipping
Free shipping with min order of ₱500

 Shipping To **Metro Manila, Metro Manila** 

Shipping Fee **₱0 - ₱40** 

Quantity - 1 + 1000 piece available


 **Shopee Guarantee** Get the items you ordered or get your money back.

Figure 5. Unregistered Dental Amalgam 1 Spill


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Up to 50% off on Colgate

Dress | Face Mask | Wallpaper | Tops | Sandals | Bras | Face Shield | Croctop

Shopee > Health & Personal Care > Medical Supplies > Dental Amalgam (2 spill)



Dental Amalgam (2 spill)

5.0 ★★★★★ | 17 Ratings | 266 Sold

₱50

Shipping Shipping To **Metro Manila, Metro Manila**
Shipping Fee **₱40 - ₱80**

Quantity 457 piece available

Shopee Guarantee Get the items you ordered or get your money back.

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Up to 50% off on Colgate

Dress | Face Mask | Wallpaper | Tops | Sandals | Bras | Face Shield | Croctop

Shopee > Health & Personal Care > Personal Care > Oral Care > Dental Amalgam 2 spills



Dental Amalgam 2 spills

No Ratings Yet | 5 Sold

₱105

Shipping **Free shipping**
Free shipping with min order of ₱500

Shipping To **Metro Manila, Metro Manila**
Shipping Fee **₱0 - ₱40**

Quantity 995 piece available

Shopee Guarantee Get the items you ordered or get your money back.

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Figure 6. Unregistered Dental Amalgam (2 spill)

The FDA verified through post-marketing surveillance that the above-mentioned medical device products are not registered and no corresponding Product Registration Certificates have 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.

In addition, with the issuance of Administrative Order No. 2020-0020 or the “Guidelines on the Phase – Out of Mercury Use in Dental Restorative Procedures”, the importation of dental amalgam capsules for use in dental restorative purposes shall not be allowed. Moreover, as stated under this Order, the phase-out period shall be within three years from effectivity after which the use of dental amalgam in the country shall no longer be allowed.

Since these unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration Certificates are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been 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 Registration number on the product label in the form of either DVR-xxx or MDR-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 these unregistered products.

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 sale or distribution of 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.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20210426110747