



13 JUL 2020

FDA ADVISORY  
No. **20201331**

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

**SUBJECT: Public Health Warning Against the Purchase and Use of Unregistered Medical Device Product David Diagnostic Kit of HCG (Colloidal Gold)**

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



Figure 1. Unregistered David Diagnostic Kit of HCG (Colloidal Gold)





The FDA verified through post-marketing surveillance that the above mentioned medical device product is not registered and no corresponding Product Registration 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 unregistered medical device has 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 Product Registration Certificate is 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](http://www.fda.gov.ph). You may also look for the FDA Registration number on the product label in the form of either RR-xxx or IVDR-xxx.

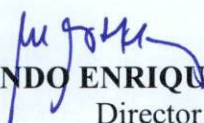
All Law Enforcement agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

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

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at [cdrrhr@fda.gov.ph](mailto:cdrrhr@fda.gov.ph), 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](http://www.fda.gov.ph/ereport).

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

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