



15 JUL 2019

**FDA ADVISORY**  
No. **2019-205**

**TO: THE GENERAL PUBLIC**

**SUBJECT: Public Health Warning Against the Purchase and Use of the following Unnotified Cosmetic Products:**

1. MAYBELLINE NEW YORK THE COLOSSAL GO EXTREME POWER (03)
2. MAYBELLINE NEW YORK THE COLOSSAL GO EXTREME VOLUM MASCARA
3. MAYBELLINE NEW YORK THE COLOSSAL GO EXTREME EYELINER
4. LIP GLOSS MATTE, LIP GLOSS STAR (03)
5. MORPHE EYELINER WATERPROOF

The Food and Drug Administration (FDA) warns the public from purchasing and using the following unnotified cosmetic products:



Figure 1. Unnotified Maybelline New York The Colossal Go Extreme Power (03)





Figure 2. Unnotified Maybelline New York The Colossal Go Extreme Volum Mascara



Figure 3. Unnotified Maybelline New York The Colossal Go Extreme Eyeliner



Figure 4. Unnotified Lip Gloss Matte, Lip Gloss Star (03)



Figure 5. Unnotified Morphe Eyeliner Waterproof



The FDA verified through post-marketing surveillance (PMS) that the abovementioned cosmetic products are not authorized and the Certificates of Product Notification have not been issued. Pursuant to 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 from FDA is prohibited.

Since these unnotified cosmetic products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The use of such violative products may pose health risks to consumers.

Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals such as Antimony (Sb) and Lead (Pb) especially in eye cosmetic products. Antimony (Sb) exposure can result to damages to the lung, heart muscle and liver. Symptoms of antimony toxicity includes skin irritation, headache, nausea, vomiting, insomnia and abdominal pain among others. Lead (Pb) exposure may cause anaemia, hypertension, renal impairment, immunotoxicity and toxicity to the reproductive organs.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)) has a *Search* feature which may be used by typing in the name of the product before purchasing.


All concerned establishments are warned not to distribute violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with Law Enforcement Agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

Kindly contact the FDA Center for Cosmetics Regulation and Research through e-mail at [ccrr@fda.gov.ph](mailto:ccrr@fda.gov.ph) or call **(02) 857-1900 local 8113 or 8107**.

To report any sale or distribution of unnotified cosmetic products, 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.

  
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