



06 September 2013

FDA Advisory
No. **2013-033**

SUBJECT: HEALTH WARNING ON BUYING UNNOTIFIED LIPSTICKS IN THE MARKET

The public is warned against buying lipsticks that are not notified with the FDA. These products may contain high levels of heavy metals, especially lead.

Heavy metals are inherently present in pigments (colorants) and in some raw materials that are used in producing lipsticks. This is due to natural contamination from the environment, which are unavoidable. Thus, the FDA enforces strict compliance to the requirements of current Good Manufacturing Practices (cGMP) for cosmetic products to ensure that possible contaminants are within the allowable limits set by the FDA, consistent with the ASEAN Directives. Studies have shown that manufacturers following strict cGMP in producing lipsticks have lead and other heavy metals way below the maximum allowable or acceptable limit.

Lead is a proven toxicant that accumulates in the body through constant exposure and absorption over a prolonged period. Health problems through chronic ingestion of high level of lead in lipsticks may manifest as neurologic, hematologic, gastrointestinal, cardiovascular, and renal problems. In adults, lead toxicant has been linked with high blood pressure, joint pain, poor memory, and concentration problems. The children are particularly at risk from neurotoxic effects of lead, which affect their brain development and cognition, like test scores, memory and learning, and fine motor skills and behavior. Lead easily crosses the placenta, and pregnant women should pay particular attention to the different sources of lead exposure.

So far, the FDA has authorized more than a hundred brands of lipstick with several color variants per brand for the consumers to choose from. All consumers are advised to buy only FDA-notified cosmetic products in the market. To check if a cosmetic product is authorized to be in the market, consumers are directed to type in the name of the product on the SEARCH bar in the FDA website (www.fda.gov.ph). Consumers may also read the product labels, packages and accompanying leaflets. Notified cosmetic products have the following written in English: a) product name, b) ingredients, c) net content, d) instruction on the use of the products, e) batch number, f) special precautions if any, and g) country of manufacture/importer.





There are unnotified products from China or imitations of the original products being sold by sidewalk and ambulant vendors or outlets in the country. The following lipsticks have no market authorization from the FDA:

1. Baolishi No. 8
2. Baolishi No. 20 (green)
3. Baolishi No. 20 (yellow)
4. Baolishi No. 25
5. Baolishi No. 37
6. Miss Beauty No. 6
7. Miss Beauty Vitamin C No. 11
8. Shijing No. 39
9. Ling Mei No. 12
10. Heng Fang No. 8
11. Popa Italy 3 in 1
12. L'Oreal No. 209
13. Luoy's Paris No. 05



Figure A. Arranged according to the list found on the left side, from Baolishi No. 8, left to right

As provided by law, the FDA calls on the assistance of all local government units and law enforcers to make sure that unnotified products being sold in their localities are confiscated.

The FDA requests the Bureau of Customs to remain vigilant in ensuring that these products are not release in the market without proper authorization from the FDA, as per requirement of FDA Memorandum Circular 2013-032, *Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs.*

To report unnotified cosmetic products in the market, please email us via report@fda.gov.ph. For inquiries and more information, kindly email us at info@fda.gov.ph.


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