Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 April 2014

FDA Advisory
No. 2014 031

SUBJECT: **Initial Findings Show that Lipsticks Tested for Lead (Pb), Arsenic (As) and Mercury (Hg) by Field X-ray Fluorescence (XRF) Instrument and the ASEAN Harmonized Laboratory Method Done by the FDA Differ Significantly**

On 17 January 2014, the FDA came out with FDA Advisory No. 2014-007, Public Caution Against Laboratory Reports on Levels of Lead (Pb) in Toys Using Handheld XRF Instrument. The FDA was seriously concerned over the field laboratory reports generated by handheld X-ray fluorescence (XRF) instruments and released to public by some well-meant organizations (http://www.fda.gov.ph/attachments/article/133050/FA2014-007.pdf).

Last February, a non-governmental organization (NGO) submitted to FDA 36 samples of lipstick products, which were not FDA-notified, and the subject of several reports published in newspapers allegedly containing prohibitive levels of lead (Pb), arsenic (As) or mercury (Hg) as measured by the XRF instrument.

All 36 products were tested by the FDA Cosmetic Laboratory using the allowable limits set by the ASEAN Cosmetic Directive (ACD) for Pb (20 ppm), As (5 ppm) and Hg (1 ppm) in cosmetic products

The FDA analysis showed that there were only 20 out of the 36 lipstick samples (55.5%) that actually contained violative levels of lead or arsenic, but none for mercury.

All 16 samples which turned out positive for lead using the XRF instrument also turned out positive when tested by the FDA using standard laboratory method. However, out of the 20 remaining samples which were negative for lead using the XRF instrument, the FDA Cosmetic Laboratory found that 2 other lipstick samples also contained lead beyond the allowable limit. The result suggests that the accuracy of the XRF instrument which is primarily used for screening heavy metals in consumer products is doubtful as a basis for consumer alert.

It is worth mentioning that out of the 14 lipstick samples which the NGO said to contain high level of mercury all turned out negative or within the allowable limit set by the ACD. Moreover, out of the 14 samples tested for arsenic beyond the allowable limit using the XRF instrument, only 2 lipstick samples turned out to be beyond the allowable limit.

The products found to contain lead and arsenic beyond the allowable limit were as follows:

A. Lead (Pb)

1	Baolishi Lipstick # 15 (Gold Case)
2	Baolishi Lipstick # 15 (Yellow Case)
3	Baolishi Lipstick # 20 (Gold Case))
4	Baolishi Lipstick # 20 (Green Case)

5	Baolishi Lipstick # 20 (Red Case)
6	Baolishi Lipstick # 20 (Yellow Case)
7	Baolishi Lipstick # 25
8	Baolishi Lipstick # 33
9	Kiss Beauty # 7
10	Kiss Beauty # 8 (Pink Case)
11	Miss Beauty lipstick # 07
12	Monaliza Lipstick # 20 (Golden Case)
13	Monaliza lipstick # 20 (with cartoon casing)
14	Monaliza Series Lipstick # 20 (GoldCase)
15	Monaliza Series Lipstick # 20 (Pink Case)
16	Monaliza Series Lipstick # 5
17	Baolishi Lipstick # 20 (Gold Case)
18	Kiss Beauty # 20

B. Arsenic (As)

19	Chanleevi #04
20	Kiss Beauty #8

The differences in accuracy of the result between a portable XRF instrument and the standard laboratory method used by the FDA indicate, among others, that the use of the XRF instruments in the field cannot be relied upon as the sole basis for alerting the consumers and the general public. All consumer alert should be based on valid scientific data. All laboratory data given out to media and public should be validated by accredited laboratories. Otherwise, inaccurate data may mislead the consumers and affect their decisions when selecting, buying and using certain health products in order to satisfy or meet their wants and needs.

The FDA fully appreciates the monitoring of consumer products being done by well-meant organizations, especially unregistered or smuggled products. However, for health products that are manufactured or distributed by FDA-licensed establishments and covered by FDA market authorization, prudence should be exercised by all sectors and stakeholders before making any unsubstantiated claim or unfounded statement.

To report adverse experience after using any cosmetic product, please email us via report@fda.gov.ph. To facilitate ADR investigation, health professionals are advised to log in at the FDA Website and click the ADR Report platform and accomplish the form on line. For more information or clarification, kindly email us at info@fda.gov.ph.

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