

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



30 March 2012

FDA MEMORANDUM CIRCULAR No. 2012-002

TO

ALL COSMETIC IMPORTERS AND MANUFACTURERS

Subject

Submission of Certificate of Analysis of Imported and

Locally-Manufactured Lipsticks

The ASEAN Cosmetic Direction provides that the ASEAN Member States shall undertake appropriate measures to ensure that only cosmetic products which conform to the Directive will be placed in the market.

Recent report from US FDA shows presence of lead in 400 lipsticks with the highest concentration of 7.19 parts per million (ppm). While the said findings is within the ASEAN limit of 20 ppm, there are consumer and environmental groups reporting excessive levels of heavy metals in lipsticks. Lipstick is considered as "high risk" for the reason that certain amount of the product may be ingested which may prove harmful or injurious to consumer.

In the interest of consumer safety, may we request you to submit the latest certificate of analysis for heavy metals (lead, mercury, arsenic and cadmium) of all lipsticks whether imported, manufactured/distributed by your company to Regulation Division I or Regulation Division II. These data will be used as reference for our Post Market Surveillance System.

For your guidance and strict compliance

SUZETTE H. LAZO, MD, FPSECP Acting Director IV