

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



12 September 2013

## FDA MEMORANDUM CIRCULAR No. 2013-03

TO

All Manufacturers, Distributors, Importers and Exporters of Toys and

Childcare Articles, including Infant Bottles and "Sippy Cups", and Other

**Concerned Parties** 

**FROM** 

KENNETH Y.HARTIGAN-GO, MD

Acting Director General

**SUBJECT** 

APPLICATION OF LICENSE TO OPERATE AND CERTIFICATE OF COMPLIANCE, AMONG OTHER TRANSCATIONS, AT CENTER FOR COSMETICS REGULATION AND RESEARCH (CCRR) FROM THE CENTER FOR DEVICE REGULATION, RADIATION HEALTH

AND RESEARCH (CDRRHR) STARTING 02 JANUARY 2014

On 06 August 2013, the Office of the Director General issued FDA Memorandum No. 2013-058, instructing the Center for Device Regulation, Radiation Health and Research (CDRRHR) to transfer the duties and responsibilities of regulating toys and childcare articles, including infant feeding bottles and "sippy cups" to the Center for Cosmetics Regulation and Research (CCRR), in compliance to the provisions of Republic Act No. 9711, otherwise known as the FDA Act of 2009, effective 13 September 2013.

With the Christmas season already fast approaching and in the interest of public service, the CDRRHR shall be given until 31 December 2013 to ensure proper training of CCRR staff to handle the regulation of toys and childcare articles, including infant bottles and "sippy cups", and complete transfer of the following: a) database on regulated establishments and their products, b) records of licensed manufacturers, distributors, importers and exporters, c) files of all License to Operate (LTO) and Certificates of Conformity (COC) issued to establishments, and d) record of all conditional release certificates issued for the immediate release of products at the Bureau of Customs, among others.

All manufacturers, distributors, importers and exporters of toys and childcare articles, including infant bottles and "sippy cups", are hereby ordered that starting on 02 January 2014 all





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applications for LTOs, COCs and other transactions with FDA shall be done at the CCRR through online notification system. All establishments shall send their Qualified Person in Industry Regulatory Affairs (QPIRA) or the official representative of the establishment to undergo a one-day training on the process of the FDA online notification application for toys and childcare articles, including infant bottles and "sippy cups". The CCRR shall announce the schedule and application to the said training in coordination with the FDA Academy by October 2013.

For more details and inquiries, you may email <u>info@fda.gov.ph</u> with a subject heading of "CCRR".

For your information and strict compliance.

