FDA MEMORANDUM CIRCULAR
No. 2014-009

Date: 04 August 2014

To: ALL MANUFACTURERS, TRADERS, DISTRIBUTORS (IMPORTERS/ EXPORTERS/ WHOLESALERS), RETAILERS AND OTHER CONCERNED PARTIES OF TOYS AND CHILD CARE ARTICLES

From: MARIA THERESA M. GUTIERREZ
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Subject: ISSUANCE OF LICENSE TO OPERATE (LTO) WITH NEW FORMAT FOR ALL TOYS AND CHILD CARE ARTICLES ESTABLISHMENTS USING THE FDA SECURITY PAPER

Please be informed that a new format of the LTO for toys and child care articles establishments shall be used by the Center following the format, content and numbering for Household/Urban Hazardous Substances (HUHS) products which shall be issued and printed using FDA Security Paper effective 04 August 2014.

The new LTO format reflect the statement that the establishment (1) is still subject to inspection by FDA authorized representatives at any reasonable time and day, as well as (2) LTO is subject to suspension or revocation anytime, should a violation of any of the provisions of R.A. 9711, and its Implementing Rules and Regulations, including but not limited to compliance to Current Good Manufacturing Practices and Good Distribution/Storage Practices, be committed.

The new LTO shall also include the clause pertaining to the notification and/or registration with FDA of all toys and child care articles to be manufactured, traded, distributed (imported, exported or sold on wholesale basis) or retailed/sold prior to their introduction to market and subject for post-evaluation and approval.

Furthermore, (1) the activity/ies as a manufacturer, trader, distributor (importer, exporter and wholesaler) and/or retailer as well as (2) the products either toys and/or child care articles shall be reflected on the second page.

For your information and guidance.