Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 February 2013

FDA MEMORANDUM CIRCULAR
No. 2013-001-A

SUBJECT: **AMENDMENT - MEMORANDUM CIRCULAR NO. 2013-001 RE: SUBMISSION OF APPLICATION FOR LICENSE TO OPERATE (LTO) AND CERTIFICATE OF PRODUCT REGISTRATION (CPR) WITH ELECTRONIC COPY (E-COPY)**

The Memorandum Circular No. 2013-001 is hereby amended as follows:

FROM	TO
4. GUIDELINES	
Section 4.1.2 The Client shall submit the above-stated requirements, properly labeled with table of contents indicating the number of pages, divider with ear tags and place them in a Data Folder with the following specifications and color per application:	**Section 4.1.2** The Client shall submit the requirements stated in Section 4.1.1, properly labeled with table of contents indicating the number of pages, divider with ear tags and place them in a Data Folder or Ordinary Folder/Filler, whichever is applicable, with the following specifications and color per application:
Specification	**4.1.2.1 Specification/Color Coding**
a. Data Folder	a. Data Folder/Ordinary Folder/Filler
Size:A4-LTO, Legal-CPR	Size: A4 (both LTO and CPR)
Thickness: 4" thick	Thickness: Any thickness applicable
3-hole binder	3-hole binder/2-hole binder/fastener – whichever is applicable.
	Color Coding per Center remains with the inclusion of: Black Data Folder/Black Ordinary Folder for Veterinary Medicine;

Civic Drive, Filinvest Corporate City, Alabang, City of Muntinlupa 1781 Philippines
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b. DVD-R (preferably in PDF searchable format at least 300dpi) shall be placed in a Hard Case – Color Coded Title Case with the ff. specification: Size: 14cm. x12.5cm. Thickness: 1 cm.

c. Application(s) with Sample shall be enclosed in an expanding plastic envelope.

4.1.2.2 All applications/submissions (clinical trial protocol, post approval changes, variations and amendments) other than applications for LTO and CPR shall follow the same format (i.e. color of binders and folders) required for each Center. For these types of applications/requests, an Electronic copy in DVD-R (preferably in PDF searchable format at least 300dpi) shall also be required;

4.1.2.3 Submission of Electronic Copy is mandatory for applications/submissions with 5 pages and above;

4.1.2.4 Table of Content

The content (hard copy/folder and e-copy) of the LTO/CPR application shall be arranged in sequential manner in accordance with the existing checklist of requirements.

4.1.2.5 Labeling of Folder/Filler & DVD-R

4.1.2.5.1 CPR APPLICATION

DRUG REGISTRATION
Company Name:_____
Generic Name:_____
Brand Name: _____
Dosage Form/Dosage Strength: _____
RSN or Application No. _____
(for compliance to NOD/ Reapplication)
DR No._____ (for renewal registration, notification & variations)

FOOD REGISTRATION

Name of Establishment: _____
Product Name: _____
FR # (if renewal): _____
Application for (x):
☐ CAT I ☐ CAT II ☐ FS
☐ Initial ☐ Renewal ☐ AR
☐Re-Application ☐Amendment ☐Re-Issuance

COSMETICS NOTIFICATION

Company's Name:_____
Date Applied: _____

MEDICAL DEVICE REGISTRATION

Company Name:_____
Product Name:_____
Address/Contact No._____
Registration No. _____
(for renewal application/ for compliance to NOD/ Reapplication/Notification/Variations)

4.1.2.5.2 LTO APPLICATION

Name of Establishment: _____
Business Address: _____
LTO # (if renewal): _____
Owner/Representative of the Company: ____
Contact Number: _____
Company email addresses: _____
Application for (x):
☐ Opening ☐ Renewal ☐ AR
☐ Amendments ☐ Re-issuance

Section 4.2 Filing of Application

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4.2.1 Payment

4.2.1. Payment

The Food and Drug Administration (FDA) in efforts to improve regulatory integrity shall minimize face-to-face interaction between clients (e.g. Liaison Officers, freelance regulatory consultants) and its regulatory

officers. Thus, there shall be no technical review, pre-assessment evaluation or checking of documents for completion prior to payment. The company's Regulatory Officer shall ensure that the submission is complete as per checklist of requirements.

4.2.1.1 The applicant shall pay the required application fee prior to submission of the electronic and hard copy of application for LTO and CPR.

4.2.1.1 The Client shall properly and completely fill-up the *Assessment Slip, which is available at the FDA Lobby, Main Building or can be downloaded in the FDA official website (www.fda.gov.ph). Then the Client shall proceed to the Billing/Cashier for the issuance of Order of Payment and Official Receipt. *(*A new Application Form/Billing Statement shall be used once the Electronic Payment takes effect).*

4.2.1.3 The Client shall ensure and guarantee that the amount to be paid is based on the latest FDA Issuances for Fees and Charges and all data indicated/declared in the Assessment Slip is true and correct otherwise the application shall be held pending (notice will be posted in the FDA website) and the Client shall be given 15 days upon posting online to correct payment. Otherwise the application will be disapproved.

Section 4.2.2. Receiving

Section 4.2.2 Receiving

Submission of application is in accordance with the existing schedule of acceptance of application by the respective Centers.

4.2.2.1 For LTO

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4.2.2.1.1 All application shall be submitted to respective Field Regulatory Operations Office (FROO);

4.2.2.1.1 All applications (and its subsequent renewals and/or amendments) from Metro Manila or the National Capital Region (NCR) shall be centrally received by the Regulatory Field Office (RFO-NCR) at the FDA-Lobby, Main Building.

4.2.2.1.2 All applications from the different provinces outside Metro Manila shall be received and processed by the respective Regional Field Offices (RFOs) and the Certificate of Compliance (COC)/ Reports and other correspondence shall be endorsed and forwarded to different Centers concerned. However, the reports for manufacturers shall be cleared and evaluated for subsequent preparation of COC by NCR-RFO;

4.2.2.1.3 All LTO applications (and its subsequent renewals and/or amendments) for Medical Devices shall be received and processed by the Center for Device Regulation, Radiation, Health and Research (CDRRHR), Manila.

4.2.2.2 For CPR

4.2.2.2 For CPR

4.2.2.2.1 All applications shall be submitted to respective Centers (Center for Drug Regulation and Research, Center for Food Regulation and Research, Center for Cosmetics Regulation and Research, Center for Device Regulation, Radiation, Health and Research).

4.2.2.2.1 All applications shall be centrally received by the respective Centers (Center for Drug Regulation and Research, Center for Food Regulation and Research, Center for Cosmetics Regulation and Research) at the FDA Lobby, Main Building except for CPR applications for Medical Devices which shall be received by CDRRHR, Manila.

Section 4.3 Evaluation of Applications

Section 4.3 Evaluation of Application

4.3.1 All received applications shall be evaluated in accordance with the prescribed requirements;

4.3.2 Incomplete requirements shall be ground for disapproval of applications and forfeiture of payment.

4.3.3 Verification of Information

All received applications shall be evaluated in accordance with the prescribed requirements and guidelines issued by the respective Centers.

4.3.3.1 LTO application shall be subjected for field inspection prior to issuance of Certificate of Compliance (COC) and subsequent issuance of LTO;

4.3.3.2 CPR application shall be subjected to technical review prior to issuance of CPR;

4.3.4 Application with NOD is subject for re-application payment; and

4.3.5 Any discrepancy of the Electronic copy of the application/product dossier against the hardcopy shall be ground for disapproval of application and/or legal action for perjury.

Section 4.4. Releasing

4.4.1 LTO and CPR shall be released to respective Centers together with the hardcopy of application for LTO/CPR;

4.4.2 Client shall keep the returned hard copy of application for LTO/CPR for a minimum of five (5) years and be made available for audit/retrieval as determine by the FDA.

4.4.3 Only authorized and accredited company's representative/liaison officer shall be allowed to receive the issued LTO/CPR.

SECTION 6 - EFFECTIVITY

Section 4.4 Releasing

4.4.1 Issuance of LTO and CPR or Notice of Deficiency (NOD)/Letter of Denial, including the hard copy of the application shall be released through Courier (Collect Payment) and/or in the Central Releasing of the Administration and Finance Office (AFO), except for LTO and CPR for Medical Devices which shall be released in CDRRHR, Manila;

4.4.2 The Client shall keep the returned hard copy of the application, retain them for 5 years after expiration of LTO/CPR and/or as long as the establishment and/or product remains active in the market, and be made available for audit/retrieval as determined by the FDA.

4.4.3 Still remains.

SECTION 6 - EFFECTIVITY / PHASED IMPLEMENTATION OF THE TERMS OF THIS MEMORANDUM CIRCULAR

6.1 This Memorandum Circular shall take effect on 04 March 2013 for all Centers and NCR-RFO;

6.2 Center for Health Development for Central Luzon (Regions 3), Center for Health Development for Southern Tagalog (Region 4-A), Center of Health Development for Western Visayas (Region 6), Center for Health Development for Central Visayas (Region 7) and Central for Health Development for Davao Region (Region 11) shall be subject to the terms and conditions of this Memorandum Circular effective 08 April 2013 while the implementation for the remaining Centers/regions shall take effect on 02 May 2013;

6.3 Section 4.1.2.1-Specification requirement for the folder (e.g. thickness, labeling and size) and Section 4.2.1.3 are given a leniency or grace period of one month prior for the strict implementation of this amendment.

For compliance.

KENNETH Y. HARTIGAN-GO, M.D.
Director General