

02 January 2013

FDA MEMORANDUM CIRCULAR

NO. 2013-001

**SUBJECT: GUIDELINES ON THE SUBMISSION OF LTO
AND CPR APPLICATION WITH ELECTRONIC
COPY (E-COPY)**

1. RATIONALE

The Food and Drug Administration (FDA) recognizes the vital role of Information and Communications Technology (ICT) for effective and efficient Records Management System.

The Republic Act No. 8792 also known as the E-Commerce Act of 2000, has provided framework and legal basis for recognizing electronic documents which were particularly reflected on Sections 7, 8, 20 & 27 of the said law (Annex 1).

The need to comply with the administrative and ethical requirements as prescribed in Section 5 (c) of Republic Act No. 6713 also known as Code of Conduct and Ethical Standards for Public Officials and Employees, which states that *"All official papers and documents must be processed and completed within a reasonable time from the preparation thereof xxx"*

2. OBJECTIVES

The submission of the soft copy or electronic file of the product dossier and company applications for product registration and license to operate aims to minimize the influx and accumulation of records in the FDA while maintaining the authenticity and reliability of the submitted electronic documentations. On the other hand, the FDA shall maintain the adherence to the confidentiality and impose security of all submitted proprietary documents in relation to the application for product registration.

The electronic submission shall mark the beginning of the electronic filing and retrieval of documents from the Administrative and Finance Office-Records Division. This act will result to the prompt retrieval of records when required by the concerned Center/s and/or clients.



3. SCOPE

The guideline shall cover all the submission of applications for product registration and license to operate for the following products: drugs, foods, cosmetics, hazardous substances/products and medical devices.

4. GUIDELINES

4.1. Requirement

4.1.1. In the application for LTO and CPR, the Client submits the necessary requirements (Annex 2 & 3 – Checklist of Requirements for LTO and CPR) prescribed by the Food and Drug Administration (FDA). In addition to the hard copy of the standard requirements, the Client shall also submit an electronic/scanned copy (in PDF Searchable Format at least 300 dpi) on a DVD-R of the application. Further, a Notarized Affidavit which states that the attached Electronic Company Application/Product Dossier is the exact duplicate of the hard copy shall also be submitted. The Client shall under no circumstances submit, copy/ transfer any unauthorised files, codes, scripts (including but not limited to viruses or worms), documents, and information;

4.1.2. The Client shall submit the above-stated requirements, properly labeled (LTO/CPR Application), 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:

SPECIFICATION	COLOR CODING
LTO Data Folder	Dark Blue - Food
Size: 4" thick, A4 Size	Green - Drug
3-hole Binder	Orange- Cosmetics
	White - Medical Devices
	Red - Household Urban/ Hazardous Substances/

Products including
Pest Control
Providers

CPR	Data Folder	COLOR CODING	
Size:	4" thick, Legal Size 3-hole Binder	Dark Blue-	Food
		Green -	Drug
		Orange-	Cosmetics
		White -	Medical Devices
		Red -	Household Urban/ Hazardous Substances/ Products including Pest Control Providers

4.2. Filing of Application

4.2.1. Payment

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

4.2.2. Receiving

4.2.2.1. For LTO

4.2.2.1.1. All applications shall be submitted to respective Field Regulatory Operations Office (FROO).

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).

4.3. Evaluation of Applications

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

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 Certificate of Product Registration (CPR);

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

4.3.5 Any discrepancy of the Electronic Company Application/Product Dossier against the hardcopy shall be a ground for disapproval of application and/or legal action for perjury.

4.4. Releasing

4.4.1. LTO and CPR shall be released to respective Centers together with the hard copy 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.

5. REPEALING CLAUSE

Previous issuances which are inconsistent with those provided in this Memorandum are hereby rescinded/repealed and/or modified accordingly.

6. EFFECTIVITY

This Memorandum shall take effect on 01 February 2013.


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