

06 June 2013

FDA Memorandum Circular  
No. 2013-023

**SUBJECT : Conversion to Electronic Copy of All Registered Drug Products' Dossier**

**1. Rationale**

Republic Act No. 8792, otherwise known as the "Electronic Commerce Act of 2000", mandates all departments, bureaus, offices and agencies of the government, including all government - owned and - controlled corporations, to accept the creation, filing or retention of documents in the form of electronic data messages or electronic documents (Part IV. Electronic Transactions in Government, Section 27. Government Use of Electronic Data Messages, Electronic Documents and Electronic Signatures).

The Food and Drug Administration (FDA) – Center for Drug Regulation and Research (CDRR) is cognizant of the need to create an information-friendly environment which supports and ensures the availability of records through the use of Information and Communication Technology (ICT) as embodied in RA 8792.

**2. Objectives**

In recognition of the important role of ICT for an effective and efficient delivery of public service, the CDRR mandates all marketing authorization holder of registered drug products to convert its product dossier into an electronic copy (e-copy) following the specifications indicated in the FDA Memorandum Circular No. 203-001-A (*Amendment – Memorandum Circular No. 2013-001 re: Submission of Application for License To Operate (LTO) and Certificate of Product Registration (CPR) with electronic copy*) and the contents are arranged in accordance with the current requirements for product registration application.

The submission of electronic documents will minimize the utilization of office space for records keeping/records storage and maximize efficiency in filing and retrieval of records of drug products. The FDA-CDRR shall adopt appropriate rules and regulations to ensure confidentiality and security of all submitted electronic documents in the use, filing and retention of such documents.



### 3. Scope

This issuance shall cover all drug products with valid Certificates of Product Registration. Drug products applied and registered from January to February 2013 prior to the implementation of FDA Memorandum Circular No. 2013-001 are also included under this Memo Circular.

### 4. Guidelines

#### 4.1 Requirement

The Marketing Authorization Holder (MAH) submits the electronic documents of each drug product arranged in accordance with the checklist of requirements for product registration application in DVD-R (preferably in PDF searchable format at least 300 dpi). The DVD-R should be placed in a hard case with thickness of 1 cm and size of 14 cm x 12.5 cm.

The DVD-R should be properly labeled with the following information :

Company Name (MAH) \_\_\_\_\_  
Generic Name : \_\_\_\_\_  
Brand Name : \_\_\_\_\_  
Dosage Form and Strength : \_\_\_\_\_  
Registration Number : \_\_\_\_\_  
CPR Validity : \_\_\_\_\_

#### 4.2 Filing and Submission

All Marketing Authorization Holders are advised to file and submit the electronic copy beginning 17 June 2013 up to 30 September 2013 at the CDRR - Receiving Section Window from 8:00 am to 5:00 pm., Mondays to Fridays. Submission of the DVD-R should come with a covering letter (in duplicate copies) that will be duly received by the CDRR.

### 5. Effectivity

This Memorandum Circular shall take effect on 17 June 2013.

  
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