



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



14 January 2014

FDA MEMORANDUM CIRCULAR
No. **2014-002**

**TO : ALL FDA DRUG LICENSED ESTABLISHMENTS and
FDA CENTERS/OFFICES**

FROM : MARIA LOURDES C. SANTIAGO
Maria Lourdes C. Santiago
Officer in Charge
Center for Drug Regulation and Research

**SUBJECT : NEW LICENSE TO OPERATE FORMAT FOR DRUG
ESTABLISHMENTS**

In line with the strengthening of the FDA's capability on licensing of all regulated establishments, a new harmonized license to operate format shall be used and issued by this Office effective 15th day of January 2014.

The new LTO format shall reflect only the pertinent information of the said establishments. Other information such as the names of the key personnel (pharmacist, production head, quality control and quality assurance manager and authorized person to release the batch) shall be shown in the LTO attachment or certification in case of amendments.

For those establishments capable of handling vaccines, biologics and other temperature-sensitive drug products, a clause stating the same shall also be reflected in compliance with the Cold Chain Management Requirement circular (BC 2007-003).

For your guidance.

MLCS/RSO/ESM/sao

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph

Fax +63 2 807 0751
Email: info@fda.gov.ph



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Management
System
www.tuv.com
ID 9105073396

