14 January 2014

FDA MEMORANDUM CIRCULAR
No. 2014-002

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

FROM : MARIA LOURDES Q. 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.