FDA CIRCULAR
No. 2015-001-A

TO: ALL DRUG MANUFACTURERS AND DISTRIBUTORS (IMPORTERS AND WHOLESALERS)

SUBJECT: Amendment to FDA Circular No. 2015-001, Clarifications on the Regulations Governing Principal and Identical Drug Products as defined under Administrative Order No. 2005-0031

With due consideration for stakeholders’ requests, the deadline for submission of applications for variations shall be up to 31 December 2015. Failure to comply with the new deadline of the principal and/or the identical drug products shall mean disapproval of renewal applications and subsequent withdrawal from the market.

For your information and strict compliance.

ATTY. NICOLAS B. LUTERO III, CESO III
OIC-Director IV
Food and Drug Administration