

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



09 February 2015

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 <u>submission</u> of <u>applications</u> shall be up to <u>31 December 2015</u>. 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



