

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



20 May 2015

FDA CIRCULAR No. 2015-003 A

TO:

ALL DRUG MANUFACTURERS AND DISTRIBUTORS

(IMPORTERS AND WHOLESALERS)

SUBJECT:

Amendment to FDA Circular No. 2015-003, Guidelines on the Implementation of New Rules and Regulations on the Licensing of Sponsors and Contract Research Organizations (CROs) following Administrative Order No. 2014-0034, dated

13 October, 2014

After due consideration of stakeholders' requests, the deadline for submission of applications for License to Operate of sponsors and CROs is extended until 31 July 2015. Failure to submit an application may mean regulatory action.

In addition, the fees for the application for LTO of the said establishments shall follow the existing fees for Drug Traders.

For your information and strict compliance.

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Secretary of Health Acting Director General1

¹ Pursuant to DPO 2015-1845

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