



23 October 2014

FDA CIRCULAR
No. 2014-018-A

TO: ALL CONCERNED GOVERNMENT-OWNED AND PRIVATE HOSPITALS, HEALTH FACILITIES, AND OTHER ESTABLISHMENTS

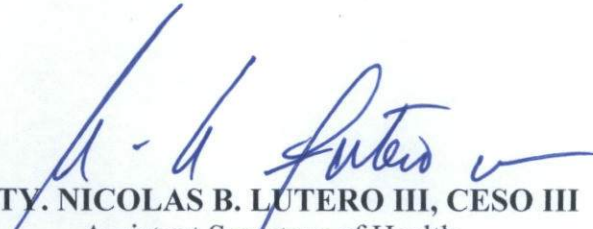
SUBJECT: Amendment to FDA Circular No. 2014-018 Dated 15 August 2014 Entitled Manufacture, Sale, and Distribution of Medical-Grade Oxygen

The last paragraph in the issuance of the Food and Drug Administration (FDA), FDA Circular No. 2014-018 dated 15 August 2014 entitled "Manufacture, Sale, and Distribution of Medical-Grade Oxygen", is hereby amended to read as follows:

"Hospitals, health facilities, and other establishments with installed and/or operating medical-grade oxygen-generating machines, as well as those presently installing the said machine, and are not duly licensed by FDA to engage in drug manufacturing processes, shall be given **six (6) months from date of effectivity to apply for License to Operate (LTO)**."

FDA's regulatory actions (i.e., suspending the use of the medical-grade oxygen-generating machine, among others) shall be enforced starting 16 February 2015 on establishments and facilities that are found non-compliant with the provisions of this Circular."

For your information and strict compliance.


ATTY. NICOLAS B. LUTERO III, CESO III
Assistant Secretary of Health
OIC, Food and Drug Administration

