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