



FDA CIRCULAR
No. 2014-018

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

FROM: 
KENNETH Y. HARTIGAN-GO, MD
Acting Director General, Food and Drug Administration

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SUBJECT: MANUFACTURE, SALE, AND DISTRIBUTION OF UNREGISTERED MEDICAL-GRADE OXYGEN

Medical-grade oxygen is classified as a drug based on existing definitions. This is available in the country in cylindrical tanks, prepared by chemical synthesis from raw materials, or from air separation machines.

FDA has received reports of the existence of oxygen-generating machines being set-up by both public and private hospitals for their own production of medical-grade oxygen, either stored initially in cylindrical tanks, or directly fed into tubes to patients. Upon regulatory inspection, review, and validation of available data on unregistered medical oxygen, the following conclusions were made:

- There is no quality assurance/quality control in place, thus safety, efficacy and quality may be compromised
- The set-up of the said oxygen-generating machines are on a manufacturing production scale level

Therefore, consistent with the mandates provided to FDA by Republic Act 9711 also known as "Food and Drug Administration (FDA) Act of 2009", and Republic Act 3720 also known as the "Food, Drug and Cosmetic Act" as amended, the FDA hereby reiterates that **establishments, including hospitals, involved in the manufacture, sale, offer for sale, and distribution of all drug products, including medical-grade oxygen are required to be licensed with FDA. Furthermore, all drug products are required to be registered before they can be manufactured, distributed, or sold.**



FDA is currently in the process of drafting specific regulations for the licensing of these hospital-based manufacturers. However, to assure the public that only safe, efficacious, and quality medical-grade oxygen gases are available, in the absence of a more specific regulation, these establishments, including hospitals, must comply with existing licensing and registration requirements:

- 1) For the licensing of these establishments:
Administrative Order No. 2012-0008, "Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Manufacturing Practice (GMP) for Medicinal Products
Administrative Order No. 56 s. 1989, "Revised Regulations for the Licensing of Drug Establishments and Outlets"
- 2) For the registration of medical-grade oxygen:
Memo: PSD02-12, "Updated Checklist of Requirements for Registration"

Compliance with the requirements of the United States Pharmacopeia, latest edition, for Oxygen is required.

Any violation from this FDA Circular and to regulations set forth by FDA shall be a ground for appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation, or revocation of existing License-to-Operate of drug outlets and establishments, and other legal actions as appropriate.

Hospitals with already established and working medical-grade oxygen-generating machines that are non-compliant with this FDA Circular shall be given **three (3) months from date of effectivity** to apply for licensing of manufacturing facility and subsequent registration of medical-grade oxygen products. During the transition period you are hereby ordered to cease and desist from using the said machine and use only FDA-registered medical-grade oxygen procured from FDA-licensed manufacturers/distributors. After **three (3) months from date of effectivity**, failure of hospitals, health facilities, other establishments to comply with this FDA Circular shall face appropriate regulatory action.

For your information and strict compliance.