



FDA MEMORANDUM
No. 2021-019

27 SEP 2021

TO: ALL OFFICERS OF THE FIELD REGULATORY OPERATIONS OFFICE AND CENTER FOR DRUG REGULATION AND RESEARCH

SUBJECT: Operation of Health Establishments/ Facilities in the Manufacture of Medical Gases without a License to Operate during the COVID-19 Pandemic

To address supply shortages brought about by the current COVID-19 pandemic, the Field Regulatory Operations Office (FROO) is directed to defer all regulatory enforcement action against health establishments/ facilities found to be engaging in the manufacture of medical gases without the requisite License to Operate (LTO); provided: such establishment/facility has an existing application for LTO and has been issued an inspection Certificate of Compliance (COC); provided further: such establishment/facility is issued an LTO within sixty (60) days from date of this issuance or the COC, whichever comes later.

The FROO and the Center for Drug Regulation and Research (CDRR) are directed to ensure dissemination of this Memorandum to all establishments/facilities with pending LTO applications for the manufacture of medical gases.

Until otherwise withdrawn, this Memorandum shall remain effective during the declared national public health emergency under Proclamation No. 922, s. 2020

For compliance of all.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

