



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 13, 2020

DEPARTMENT CIRCULAR

No. 2020- 0175

TO: ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO); EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS AND NATIONAL NUTRITION COUNCIL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; PRESIDENT OF THE PHILIPPINE HEALTH INSURANCE CORPORATION; DIRECTORS OF PHILIPPINE NATIONAL AIDS COUNCIL AND TREATMENT AND REHABILITATION CENTERS, AND ALL OTHERS CONCERNED

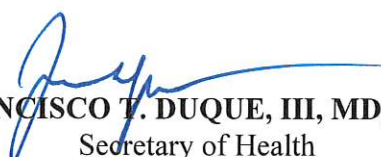
SUBJECT: Reiteration of Food and Drug Administration Circular 2020-014 on the Interim Guidelines on the Manufacture of Personal Protective Equipment (PPE), Ventilators, and Respirators in Light of the COVID-19 Situation

The World Health Organization declared the outbreak of Coronavirus Disease 2019 (COVID-19) as a pandemic last March 11, 2020. This has led to a shortage of personal protective equipment (PPE), ventilators, respirators, and other medical devices crucial in the prevention of infection and management of the disease.

The Department of Health hereby reiterates the interim guidelines as specified by Food and Drug Administration (FDA) Circular No. 2020-014 in order to facilitate the manufacture of local PPE and other innovations.

FDA Circular No. 2020-014 shall apply to all establishments that intend to manufacture PPE, ventilators, respirators, and other related innovations. They must secure a License to Operate (LTO) from the FDA as manufacturers of medical devices, and shall only begin production once this is secured. They shall not be required to secure a Certificate of Product Notification or Registration during the period of public health emergency. However, manufacturers who intend to continue production after the state of public emergency must apply for product notification / registration within three (3) months after the lifting of such state of public health emergency.

Dissemination of the above information is requested.


FRANCISCO T. DUQUE, III, MD, MSc
Secretary of Health



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



08 APR 2020

FDA CIRCULAR
No. 2020-014

TO: ALL CONCERNED STAKEHOLDERS AND PARTIES

SUBJECT: Interim Guidelines on the Manufacture of Personal Protective Equipment (PPE), Ventilators, and Respirators in Light of COVID-19 Situation

I. RATIONALE

The outbreak of Corona Virus Disease (COVID-19) has been declared as a pandemic by the World Health Organization and as a public health emergency by the national government. Due to this pandemic, there has been a continuous rise in the number of hospitalized patients which consequently resulted in the increase in the demand for PPE, ventilators, and respirators to manage severe cases of COVID-19.

II. OBJECTIVE

To provide guidance to the companies and institutions signifying their interest to manufacture PPE, ventilators, and respirators to address the COVID-19 public health emergency situation, this Circular is hereby issued.

III. GUIDELINES

All establishments that intend to manufacture PPE, Ventilators, and Respirators are required to secure a **License to Operate (LTO) as medical device manufacturer**. The requirements for application of LTO are listed in Annex A of this Circular based on Section VI-A and VI-B of the Administrative Order (A.O) No. 2016-0003 entitled "*Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration*". Copy of the A.O can be downloaded at: <http://ww2.fda.gov.ph/attachments/article/303720/Administrative%20Order%20No.%202016-0003.pdf>

Manufacturers who intend to continue to produce PPE, Ventilators, and Respirators for commercial use shall apply for product notification/registration within three (3) months after the lifting of the State of Public Health Emergency throughout the Philippines (Proclamation NO. 922 s. 2020) in compliance with AO No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements". For manufacturers who will only operate within the public health emergency period, no product registration/notification shall be required.

The development, design, functionality/performance testing, product validation, risk management, sterilization, clean room environment, clinical trial (whichever is applicable), and other considerations in the manufacture of these products shall be guided by the following:

1. Philippine National Standard (PNS);
2. Applicable International Standards (ISO or IEC), in the absence of the PNS; and
3. Technical requirements for the registration of these medical devices as stated in Administrative Order No. 2018-0002: Guidelines Governing of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements

Testing of the finished product to ensure the quality and safety shall be done by the appropriate accredited laboratory by the Philippine Accreditation Bureau.

IV. EFFECTIVITY

This Circular shall take effect immediately and shall remain valid unless otherwise revoked, repealed, or rescinded.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Annex A

Application Requirements and Process for LTO

A. Initial application

1. Accomplished Application Form and Declaration and Undertaking
2. Proof Business Name Registration
3. Site Master File (for manufacturers of drugs, devices, and cosmetics)
4. Risk Management Plan
5. Payment

B. Application Process

1. Filing
2. Evaluation
3. Inspection

Pre-opening inspection shall be mandatory for manufacturers. All covered establishments may be inspected at any time by FDA as part of its post-marketing surveillance activities.

Guidance for the above requirements can be seen on Administrative Order 2016-0003