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 Internationals 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