Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA CIRCULAR
No. 2020-031

03 NOV 2020

SUBJECT: **Updated Guidelines on the Importation and Manufacture of Personal Protective Equipment (PPE), Ventilators and Respirators used in the COVID-19 Pandemic**

I. RATIONALE

Due to the rapid spread of the COVID-19 disease, the Philippines was placed under a State of Public Health Emergency last 8 March 2020. Shortly thereafter, the World Health Organization declared COVID-19 as a pandemic in light of the rising reported cases and sustained risk of further global transmission.

There is high demand for Personal Protective Equipment (PPE), Ventilators and Respirators as a result of the public health emergency. To avoid bottlenecks in the entry of said health products in the local commercial market, the Food and Drug Administration (FDA) has streamlined procedures to ensure smooth inflow of PPEs, Ventilators and Respirators intended for commercial use or donation under FDA Advisory Nos. 2020-547 and 2020-449 and FDA Circular No. 2020-014.

The guidelines were consolidated and updated in FDA Circular 2020-018 entitled *"Interim Guidelines on the Importation and Manufacture of Personal Protective Equipment (PPE), Ventilators and Respirators to be used in the COVID-19 Pandemic."*

Under said Circular, all establishments which intend to import or manufacture COVID-19 related PPE and Ventilators and Respirators were required to secure a License to Operate (LTO) as medical device importer.

Importers and manufacturers of PPEs were advised to secure a Certificate of Product Notification ("CPN," otherwise referred to as Certificate of Medical Device Notification [CMDN]) prior commercial sale and distribution of said products. Importers and manufacturers which have started to sell their products without product notification were advised to apply for said certificate within three (3) months from effectivity of the issuance, or from 26 May 2020 until 25 August 2020.

With respect to Ventilators and Respirators, importers and manufacturers thereof were advised to apply for a Certificate of Product Registration (CPR) within three (3) months after lifting of the State of Public Health Emergency throughout the Philippines (Proclamation No. 922 s.2020).

Considering that adequate supply of the foregoing health products has already been established, and considering further that sufficient time has already passed to afford stakeholders reasonable opportunity to comply with marketing authorization requirements, there is a need to update the guidelines for the importation and manufacture of PPE, Ventilators and Respirators used in the COVID-19 Pandemic.

II. OBJECTIVE

To provide and update guidelines for the procedure for customs release for PPE, Ventilators and Respirators to be used in the COVID-19 Pandemic.

III. GUIDELINES

PPE to be used in the COVID-19 Pandemic shall refer only to face masks for medical use including N95 Masks, surgical masks, shoe covers, gloves, head covers and gowns. Ventilators and Respirators shall include Respiratory Therapy Devices and their respective accessories.

Further, importers and manufacturers of devices that are similar in terminology but are not for medical use shall not be considered as medical devices. Such establishments need not secure a LTO or a CMDN/ CPR for their products.

The importation and manufacture of such medical devices shall adhere to the following guidelines:

A. Licensing and Notification/Registration Requirements

1. PPE

All establishments which intend to import and manufacture PPE to be used in the COVID-19 Pandemic are required to secure an LTO as medical device importer or manufacturer, as may be proper pursuant to Administrative Order (AO) No. 2016-0003 as amended by AO No. 2020-017.

After securing the LTO, importers and manufacturers of PPE are required to secure a CMDN prior commercial sale and distribution of said medical devices pursuant to AO No. 2018-0002 entitled *"Guidelines Governing the Issuance of the Authorization for Medical Device based in ASEAN Harmonized Technical Requirements."*

2. Ventilators and Respirators

All establishments which intend to import and manufacture Ventilators and Respirators are required to secure an LTO as medical device importer or manufacturer, as may be proper pursuant to AO No. 2016-0003 as amended by AO No. 2020-017.

After securing the LTO, licensed establishments shall be required to secure a CPR pursuant to AO No. 2018-0002 within a period of six (6) months from date of effectivity of this Circular.

3. Guidelines for Manufacturing of PPE, Ventilators and Respirators

Manufacturers which intend to secure product authorizations for PPE, Ventilators and Respirators shall be guided by the following standards with respect to the development, design, functionality/performance testing, product validation, risk management, sterilization, clean room environment, clinical trial (whichever is applicable), and other relevant considerations:

3.a. Philippine National Standards (PNS),
3.b. Applicable International Standards International Standards Organization (ISO) or International Electrotechnical Commission (IEC), in the absence of the PNS, and
3.c. Technical Requirements for registration as provided under AO 2018-0002.

4. Regulatory Action against Erring Establishments and Violative Products

All concerned establishments are enjoined to comply with the foregoing guidelines. Strict post-market surveillance shall be implemented. Non-compliance shall result to proper regulatory action including but not limited to closure of erring establishments and seizure of violative products as provided under pertinent provisions of R.A. No. 9711 and other applicable administrative issuances.

B. Customs Release of PPE, Ventilators and Respirators

1. PPE

For PPE intended for entry to the local market for commercial use, the presentation of the LTO as medical device importer and the CPN/CMDN for the imported PPE shall serve as FDA clearance for customs release.

2. Ventilators and Respirators

Within a period of six (6) months from date of effectivity of this Circular, licensed establishments shall be allowed to import Ventilators and Respirators with only a valid LTO as importers. Thereafter, a CPR shall also be required prior to customs release.

3. Customs Release of donated PPE, Ventilators and Respirators

For foreign donations of PPE, Ventilators and Respirators, clearance from the FDA shall not be needed. These include importation of companies, other than medical device establishments, with employees who use face masks in the performance of their jobs and strictly for company use.

IV. REPEALING CLAUSE

This order repeals FDA Circular 2020-018. All other issuances or parts thereof inconsistent with the provisions of this Circular are hereby repealed or modified accordingly.

V. EFFECTIVITY

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

ROLANDO ENRIQUE D. DOMINGO, MD
Director General