Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

26 MAY 2020

FDA CIRCULAR
No. 2020-018

TO: **ALL CONCERNED STAKEHOLDERS AND PARTIES**

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

I. RATIONALE

Due to the alarming level of spread and severity of Corona Virus Disease (COVID-19), the World Health Organization (WHO) officially declared the virus outbreak a pandemic on 11 March 2020. Subsequently, the President of the Philippines declared a State of Public Health Emergency and State of Calamity due to COVID-19 through Proclamation Nos. 922 and 929, respectively.

Demand for essential medical devices used in the response to COVID-19 such as Personal Protective Equipment (PPE), ventilators and respirators has increased. Said PPE pertains to face masks including N95 masks, shoe covers, gloves, head covers and gowns. On the other hand, the ventilators and respirators include respiratory therapy devices and respective accessories.

In turn, the Food and Drug Administration (FDA) has adopted several measures to ensure adequate access and availability of said medical devices to the general public.

Considering that there is now adequate supply of medical devices used for the COVID-19 Pandemic, concerns regarding safety and quality of these products have grown. Hence, in order to ensure safety and quality of the medical devices used in the COVID-19 pandemic, the following guidelines are hereby adopted.

II. OBJECTIVE

To provide guidelines to the companies and institutions engaged or shall engage in importation and manufacture of PPE, ventilators and respirators to be used in the COVID-19 Pandemic.

III. GUIDELINES

A. Licensing and Registration Requirements

All establishments which intend to import or manufacture PPE, ventilators and respirators to be used in the COVID-19 Pandemic are required to secure a License to Operate (LTO) as medical device importer or manufacturer, as may be proper pursuant to Administrative Order (AO) No. 2016-0003 entitled *"Guidelines on Unified Licensing Requirements and Procedures of the Food and Drug Administration."*

After securing the required LTO, importers and manufacturers of PPE are advised to apply for a Certificate of Product Notification (CPN) prior commercial sale and distribution of the medical devices.

On the other hand, importers and manufacturers of ventilators and respirators are advised to apply for a Certificate of Product Registration (CPR) within three (3) months after the lifting of the State of Public Health Emergency throughout the Philippines (Proclamation No. 922 s. 2020).

The application for the CPN/CPR shall comply with the requirements of AO No. 2018-0002 entitled *"Guidelines Governing the Issuance of the Authorization for a Medical Device based in ASEAN Harmonized Technical Requirements."*

Manufacturers which intend to secure product authorizations for medical devices to be used in COVID-19 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:

1. Philippine National Standards (PNS),
2. Applicable International Standards (ISO or IEC), in the absence of the PNS; and
3. Technical requirements for registration as provided under AO No. 2018-0002.

Authorized importers and manufacturers of medical devices used in COVID-19 which have started to sell and distribute their products without product notification/ registration under FDA Advisory Nos. 2020-547 and 2020-449 and FDA Circular No. 2020-014 are advised to apply for a Certificate of Medical Device Notification (CMDN) or Certificate of Product Registration (CPR) within three (3) months from effectivity of this Circular. Strict post-market surveillance shall be implemented to all PPE, ventilators and respirators. Non-compliance to this requirement shall result to proper regulatory action.

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.

B. Procedure for Customs Release

For PPE, ventilators and respirators intended for entry to the local market for commercial use, the presentation of the copy of the importer's LTO shall be sufficient compliance for customs release.

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

Said procedure for clearance of PPE, ventilators and respirators prior to customs release shall be in effect until otherwise lifted.

IV. REPEALING CLAUSE

This Circular repeals FDA Advisory Nos. 2020-547 and 2020-449, and FDA Circular No 2020-014. 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.

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Director General