Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-018

13 SEP 2021

SUBJECT: **UPDATED GUIDELINES ON THE IDENTIFICATION, NOTIFICATION, EVALUATION, REGULATORY ENFORCEMENT ACTION, AND REVIEW AND MONITORING OF DONATED HEALTH PRODUCTS SOLELY INTENDED TO ADDRESS COVID-19 PUBLIC HEALTH EMERGENCY**

I. INTRODUCTION

Due to the COVID-19 Pandemic, COVID-19 donations of certain health products such as Personal Protective Equipment (PPE), Diagnostic Test Kits, Alcohol, Sanitizers, Soaps, Ventilator and Respirators have increased.

Donations of health products to the Department of Health (DOH) for the COVID-19 Pandemic were referred to the Food and Drug Administration (FDA) for evaluation under Administrative Order No. 2007-0017 entitled or the *"Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency and Disaster Situation."*

In order to increase access to essential COVID-19 health related products, the FDA has expedited the processing of evaluation of donations of COVID-19 health products intended for the COVID-19 Pandemic.

On 18 March 2020, FDA Circular No. 2020-009, entitled *"Guidelines on the Identification, Notification, Evaluation, Regulatory Enforcement Action, and Review and Monitoring of Donated Health Products Solely Intended to Address COVID-19 Public Health Emergency,"* was issued to streamline the process of evaluation for donated COVID-19 related health products. The guidelines were reissued as FDA Circular No. 2020-022 last 30 May 2020.

For the proper facilitation and management of donated COVID-19 the DOH has issued Administrative Order No 2021-0022 or the *"Guidelines on the Facilitation and Management of Donations to the Health Sector During the COVID-19 Pandemic."* As provided in Administrative Order No 2021-0022, FDA has the role of "providing technical assistance on the evaluation of donated items."

These guidelines are being issued to update and further streamline the regulatory process governing donated health products solely intended to address COVID-19 public health emergency.

II. OBJECTIVE

This Circular aims to provide the guidelines on the identification, notification, evaluation, regulatory enforcement action, and review and monitoring of donated health products solely intended to address COVID-19 public health emergency referred by the DOH.

III. SCOPE

This Circular applies only to the following health products:

1. Face Masks including N-95 Masks,
2. Shoe Covers,
3. Gloves,
4. Head Covers,
5. Gowns,
6. Goggles/ Face Shields,
7. COVID-19 Diagnostic Test Kits,
8. Alcohol, Hand Sanitizers, Soaps, etc.,
9. Ventilators, Respirators, their respective Accessories, and Respiratory Devices, and
10. Health Products associated with the conduct of COVID-19 Vaccination such as but not limited to diluents, syringes and gloves form the COVAX Facility/ World Health Organization, except vaccines and drugs.

Other health products that may hereinafter be identified shall be listed by the FDA through advisories.

IV. GUIDELINES

A. Identification of covered health products

1. The health products identified and listed above are covered by this Circular, whether locally or foreign donated.
2. The CDRR, CDRRHR, CCHUHSRR and CFRR shall identify and recommend other health products that may be covered by this Circular hereinafter.
3. Once the recommendation is approved, the FDA shall provide a listing which shall form part of this Circular.

B. Notification

1. Documentary requirements for donations provided in DOH Administrative Order No. 2021-0022 or the "Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency and Disaster Situations" shall be received by the FDAC for notification purposes.
2. Once the complete set of documents has been received by FDAC from the DOH, the donated covered health products are immediately deemed cleared as required under Administrative Order No. 2007-

0017. The receiving copy of such documents shall be bear the note/stamp '**RECEIVED AND CLEARED FOR "COVID-19" DONATION PURPOSES,'** and shall be sufficient clearance from the FDA. However, the donated products shall be subject to post-notification evaluation and further regulatory or enforcement action by the FDA.

3. All documents received by the FDAC shall be endorsed to the appropriate Center with urgency.

C. Post-notification Evaluation

1. Once endorsed, the appropriate Center shall evaluate the documents and notify the FROO for the collection of samples.
2. The assigned inspector(s) shall expediently collect samples and forward the same to the appropriate Center and to the Laboratory in case testing is required.
3. Should testing be required, the Testing Laboratories shall immediately conduct the appropriate analysis/assay and issue the corresponding report. The report including results of evaluation shall be forwarded to the Bureau of International Health Cooperation (BIHC) or other assigned DOH Office, as may be proper.

D. Regulatory Enforcement Action

1. If evaluation shows that the health product is unsafe or unfit for the purpose it is intended, immediate regulatory or enforcement action shall be pursued by the FROO in coordination with the concerned Center. Regulatory or enforcement action shall include, recall, seizure, and/or filing of legal case before the FDA or in court.
2. Close coordination by the FROO with Bureau of Customs (BOCs), DOH, Local Government Units (LGUs), Law Enforcement Agencies, and other concerned government agencies is mandated.

E. Review and Monitoring

The Policy and Planning Service (PPS), in coordination with the concerned Centers and Offices, shall continuously monitor the implementation of this Circular. Any necessary changes shall be immediately recommended to the Office of the Director General for approval.

V. REPEALING AND SEPARABILITY CLAUSE

FDA Circular No. 2020-009 reissued as FDA Circular No. 2020-0022, and all amendments thereto, and all other provisions in existing circulars and memoranda are hereby withdrawn, repealed and revoked accordingly.

If any provision in this Circular is held invalid, the remainder thereof shall not be affected.

VI. EFFECTIVITY

This Order shall take effect immediately and shall be in effect until 31 December 2021 unless sooner revoked or extended.

For the information and guidance of all.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General