Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

19 MAR 2020

FDA CIRCULAR
No. 2020-009

SUBJECT: **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

The Corona Virus Disease (COVID-19) outbreak has been declared as a pandemic. A State of Public Health Emergency throughout the Philippines is in effect, and enhanced Community Quarantine was declared. Undeniably, the country is in the midst of a emergency brought about by the COVID-19 disease posing a clear and present danger to the health and lives of the public.

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.

III. Bases

This Circular is issued pursuant to Department of Health (DOH) Administrative Order No. 2007-0017 dated 28 May 2007,[1] pursuant to the authority and mandate of the Food and Drug Administration (FDA) to protect and promote the right to health of the Filipino people under the 1987 Constitution and Republic Act No. 3720, as amended by Executive Order No. 175 and Republic Act No. 9711, Republic Act No. 11332[2], and Republic Act No. 10121.[3]

[1] "Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency and Disaster Situations"
[2] "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act"
[3] Philippine Disaster Risk Reduction and Management Act of 2010

IV. Scope

This Circular implements the process of identification, notification, evaluation, review and monitoring and other regulatory or enforcement action of FDA covering foreign or locally donated health products solely intended to address the COVID-19 public health emergency.

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, etc., and
9. Other health products that may hereinafter be identified and listed by the FDA.

All the offices within the FDA, principally the Food and Drug Action Center (FDAC), Center for Drug Regulation and Research (CDRR), Center for Device Regulation, Radiation Health, and Research (CDRRHR), Center for Cosmetics Regulation and Research (CCRR), Center for Food Regulation and Research (CFRR), Field Regulatory Operations Office (FROO), and Testing Laboratories are mandated to perform, with dispatch, their respective functions in implementing this Circular.

V. 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, CCRR 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 and shall form part of this Circular.

B. Notification

1. Documentary requirements for donations provided in DOH Administrative Order No. 2007-0017 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.

The receipt, endorsement to the appropriate Center, evaluation by the Centers and issuance of reports shall in no case exceed forty eight (48) hours.

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.

All involved Centers and Offices shall submit reports to the Office of the Director General every 48 hours or earlier as necessary of any development in the implementation of this Circular."

VI. Effectivity

This Order shall take effect immediately and shall be in effect until 30 May 2020 unless sooner revoked or extended.

For your information and guidance.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General