



**JOINT MEMORANDUM CIRCULAR NO. 01
Series of 2020**

FOR: ALL IMPORTERS OF PERSONAL PROTECTIVE EQUIPMENT (PPE) AND SPECIFIC MEDICAL DEVICES ESSENTIAL FOR THE MANAGEMENT OF COVID-19 FOR COMMERCIAL DISTRIBUTION

SUBJECT: CREATION OF BAYANIHAN ONE STOP SHOP FOR SECURING LICENSE TO OPERATE (LTO) TO IMPORT COVID-19 CRITICAL COMMODITIES FOR COMMERCIAL DISTRIBUTION

DATE: 02 APRIL 2020

I. BACKGROUND

The declaration of a State of Calamity by President Rodrigo Duterte through Presidential Proclamation 929 on March 16, 2020 and the imposition of an Enhanced Community Quarantine (ECQ) in Luzon as a consequence of the spread of the Corona Virus Disease ("COVID-19"), resulted to a lot of streamlining efforts by various government agencies in procedures involving critical government services. These efforts were initiated as the need to reduce and/or avoid person-to-person contact in processing necessary permits and authorizations have become increasingly necessary, including those intended for the importation of Personal Protective Equipment ("PPE") and specific medical devices essential for the management of ("COVID-19 Critical Commodities").

Despite the streamlining efforts of concerned government agencies, bottlenecks and challenges in the importation process remain. This is particularly true with respect to commercial importations of COVID-19 Critical Commodities. Among these are the following:

- (a) confusion and misinformation of the public on procedures for commercial importations of COVID-19 Critical Commodities by private entities; and
- (b) continued operation of government agencies under a "silo system" where applicants need to transact with individual government agencies separately, even if they are part of the entire importation process.¹

¹ **FDA Circular No. 2020-006**, *Guidance for Applications and Transactions at the Food and Drug Administration in light of the Community Quarantine Declaration*, dated 17 March 2020; **FDA Circular No. 2020-009**, *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* dated 19 March 2020; **FDA Circular No. 2020-009-A**, *Amendment to Include Ventilators*,

Needless to say, even if each agency involved in the importation process streamline its procedures and reduce documentary requirements, applicants still deal with the government on a “piece-meal” basis. This means that any delay or challenge in one government agency produces a domino effect across the other import processing agencies, which becomes unduly burdensome to the importer.

There is, thus, an increasing public clamor and need for more efficient inter-connected processes, particularly in the **commercial importation of COVID-19 Critical Commodities**. For emphasis, this does not cover the clearance of relief consignments entered during a state of calamity which is already covered by Joint Administrative Order No. 1-2020.²

II. PURPOSE

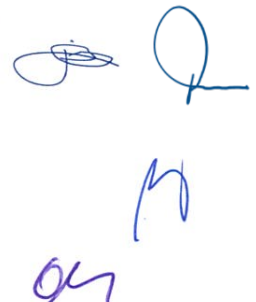
The creation of Bayanihan One Stop Shop (BOSS) is hereby adopted through the joint efforts of the Bureau of Customs (BOC), Food and Drug Administration (FDA), and Anti-Red Tape Authority (ARTA) pursuant to the relevant provisions of **Republic Act No. 11469** or the “Bayanihan to Heal as One Act” (the “Bayanihan Act”). Section 4 of the Bayanihan Act grants the President the power to adopt certain temporary emergency measures to respond to the crisis brought by the COVID-19 pandemic, including among others, the following:

- (a) To continue to enforce measures to protect the people from xxx other **pernicious practices affecting the supply, distribution and movement of xxx sanitation products, medicine and medical supplies, and other articles of prime necessity, whether imported or locally produced or manufactured (Section 4 (i))**;
- (b) To ensure that **donation, acceptance and distribution of health products intended to address the COVID-19 public health emergency are not unnecessarily delayed** and that **health products for donation** duly certified by the regulatory agency or their accredited third party from countries with established regulation shall **automatically be cleared**: *Provided*, That this shall not apply to health products which do not require a certification or clearance from Food and Drug Administration (FDA) (**Section 4(j)**); and

Respirators and their Respective Accessories to the List of Medical Devices Covered by FDA Circular No. 2020-009, dated 27 March 2020.

BOC OCOM Memorandum No 62-2020, *Guidelines for the Issuance of Accreditation Pass to BOC Stakeholders*, dated 25 March 2020; BOC OCOM Memorandum No. 61-2020, *Online Filing of Goods Declaration*, dated 24 March 2020; BOC OCOM Memorandum No. 60, *Suspension of the 7-day period to Lodge Goods Declaration During the Enhanced Community Quarantine*, dated 23 March 2020; BOC OCOM Memorandum No. 57-2020, *Extension of Validity of Accreditation of Stakeholders During the Community Quarantine*, dated 19 March 2020.

² Clearance of Relief Consignments Entered During a State of Calamity, dated 16 March 2020



- (c) To liberalize the grant of incentives for the manufacture or importation of critical or needed equipment or supplies for the carrying-out of the policy declared herein, including healthcare equipment and supplies: *Provided*, That importation of these equipment and supplies shall be **exempt from import duties, taxes and other fees (Section 4 (o))**. [Emphasis supplied]

III. COVERAGE

The operation of the Bayanihan One Stop Shop (BOSS) shall cover all commercial importation of Personal Protective Equipment (PPEs) and specific medical devices determined as “COVID-19 Critical Commodities” by the Department of Health (DOH), which require a License To Operate (LTO) from FDA. Please see **Annex “A”** for the complete list of covered items as of 02 April 2020³.

IV. GUIDELINES

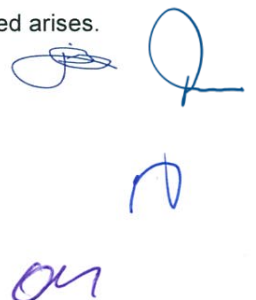
The Bayanihan One Stop Shop (BOSS) is a single window and concierge for all government agencies involved in the importation of COVID-19 Critical Commodities. Specifically, two agencies are involved, *to wit*: **(a) the Food and Drug Administration (“FDA”)**; and **(b) the Bureau of Customs (“BOC”)**. Under normal conditions, importations of COVID-19 Critical Commodities regulated by the FDA will require the issuance of the relevant License to Operate (LTO) to the importer and registration or notification of every health product unless explicitly exempted. The importer will then be required to present this LTO and/or the Certificate of Product Registration (CPR)/Notification to the BOC for the latter to clear the commodities for entry into the country.

To further streamline the procedure and for improving communication among agencies, BOSS shall operate under the following process:

1. A single window to accept all online applications for importation of covered items.
2. Interconnection of systems and portals of the concerned agencies. BOC’s, FDA’s, and ARTA’s respective websites are now linked to each other to have an end-to-end processing and monitoring of applications.

A BOSS online platform (i.e. Viber group chat) composed of FDA, BOC, SEC, DTI, CDA, GCG, and ARTA is likewise created to track all incoming importations for processing.

³ List of COVID-19 Critical Commodities is subject to modification by the DOH as the need arises.

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3. All transactions with FDA and BOC shall be done online through the following websites⁴:

Food and Drug Administration (FDA) – LTO Application

http://boss.fda.gov.ph/applications/license_to_operate/medical_device/distributor/initial

Bureau of Customs (BOC) – application for Clearance and Release of Shipment

<https://client.customs.gov.ph/index.php>

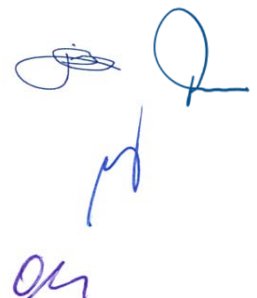
Once an application for importation, or for LTO, is entered into either BOC or FDA portal, concerned agencies shall be automatically prompted through the BOSS platform and e-mail for information and monitoring purposes. In case there is a need to verify the importer's legitimacy to do business, SEC (for private corporations/partnership), DTI (for sole proprietorships), CDA (for cooperatives), or GCG (for GOCCs), may immediately validate.

4. All FDA laws, rules and regulations governing post-importation (i.e., distribution, advertisement, use and disposal) of imported COVID-19 Critical Commodities covered by this issuance shall, however, be complied with.
5. When the national public health emergency has been lifted, all FDA rules and regulation on registration of health products, post-LTO inspection of establishment and post-market surveillance shall apply to the establishments which were issued the provisional LTO and all their health products.
6. ARTA, consistent with its mandate, is hereby designated to act as general coordinator for the seamless processing and exchange of information between and across the agencies concerned.
7. Daily and weekly reports of total number and volume of imported COVID-19 Critical Commodities that were facilitated through the Bayanihan One Stop Shop (BOSS) are to be submitted to the Inter-Agency Task Force for monitoring and validation purposes. This may then be incorporated as part of the Weekly Report of the President to the Congress as provided in Section 5 of R.A. 11469.

V. EFFECTIVITY

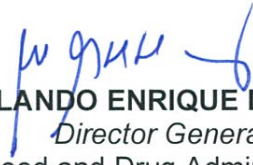
The Business One Stop Shop (BOSS) shall be operative starting the **3rd day of April 2020** and shall be in effect only until the existence of the State of National Emergency or until otherwise required by the President.

⁴ A general process is hereto attached as **Annex "B"** for reference.





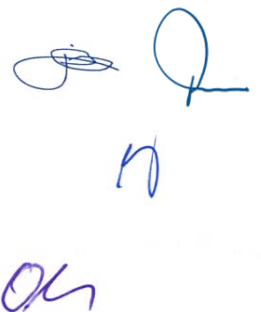
REY LEONARDO B. GUERRERO
Commissioner
Bureau of Customs



ROLANDO ENRIQUE DOMINGO
Director General
Food and Drug Administration



ATTY. JEREMIAH B. BELGICA
Director General
Anti-Red Tape Authority



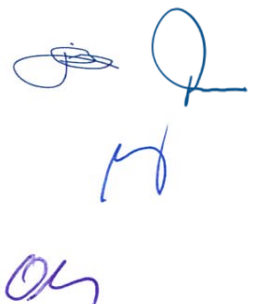
ANNEX "A"

LIST OF COVID-19 CRITICAL COMMODITIES (as of 2 April 2020*)

- I. Personal Protective Equipment (PPE):
 - A. Gloves
 - B. Gowns
 - C. Coveralls
 - D. Body Suits
 - E. Face Masks
 - F. Goggles
 - G. Face shields
 - H. Shoe Cover
 - I. Head Cap/Cover
 - J. Boots

- II. Other specific medical devices
 - a. Adhesive, All types (Adhesive Tape, Adhesive Bandage)
 - b. Anchor, preformed
 - c. Bandage
 - d. Base paste
 - e. Cannula, Reusable
 - f. Cap (Disinfection, Seal, Taper, Dead End)
 - g. Clinical Thermometer, Analog type (Except mercurial type)
 - h. Cotton (Medical/Hospital Use)
 - i. Dressing
 - j. Flowmeter (All Types)
 - k. Gauze
 - l. Gloves, Examining, Non-sterile gloves
 - m. Lubricating Gel/Jelly (External, Internal)
 - n. Luer Lock
 - o. Nasal Spray (Without Claims)
 - p. Nasopharyngeal Airway
 - q. Stop Cock
 - r. Surgical Drape, Sterile
 - s. Syringe without needle
 - t. Tape, surgical/medical

**may be updated as determined by the Department of Health (DOH)*

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ANNEX "B"

Bayanihan One Stop Shop (BOSS) General Process*

FOOD AND DRUG ADMINISTRATION (FDA) [application for License To Operate (LTO)]

STEP 1: SUBMISSION and EVALUATION

1. Applicant shall electronically file his/her application for LTO through the FDA's portal (<http://boss.fda.gov.ph/applications>)

Internal: Once an application is received by FDA, it shall post the information on the BOSS Viber group for all agencies' information and tracking.

2. Upon submission to FDA, it shall evaluate the application for completeness and correction and then send an "Order of Payment" to the applicant through e-mail, copy furnished to BOC and ARTA.

NOTE: FDA's "Order of Payment" shall now be used by the applicant to process his/her importation application with the BOC while waiting release of e-LTO.

Internal: In case there is a need to verify the importer's business registration, FDA shall send a Viber message to SEC (for private corporations/partnership), DTI (for sole proprietorships), CDA (for cooperatives), or GCG (for GOCCs), for immediate verification.

STEP 2: PAYMENT

Upon receipt of Order of Payment, the applicant may pay the application fee through any of the following payment channels:

- **Online** at www.bancnetonline.com – through the Development Bank of the Philippines (DPB)

Account No: 0430-037576-030

Total Amount: P4,055.00 (inclusive of P15.00 convenience fee)

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- **Over-The-Counter (OTC)**
 - Through Land Bank of the Philippines (LBP) On-Call Payment Facility (please use On-Coll Payment Slip)
Account No: 0392-2220-30
Total Amount: P4,040.00

Once payment is made, applicant shall send a proof of payment to FDA Cashier's e-mail address (cashier@fda.gov.ph), copy furnished to BOC and ARTA.

STEP 3: ISSUANCE OF ELECTRONIC LTO (e-LTO)

The FDA CDRRHR shall issue the electronic LTO (e-LTO) after the Cashier has posted payment. Printing of the e-LTO shall be done by the applicant.

FDA shall conduct a post-audit to validate the payment of the among others.

BUREAU OF CUSTOMS (BOC)
[application for importation]

STEP 1: SUBMISSION and EVALUATION

Importer shall electronically file his/her application through the BOC's portal (<https://client.customs.gov.ph/index.php>)

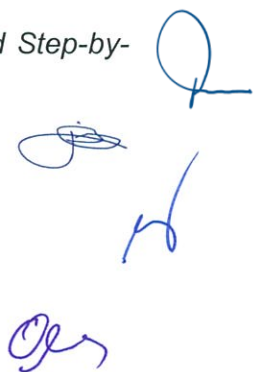
Internal: Once an application is received by BOC, it shall post the information on the BOSS Viber group for all agencies' information and tracking.

STEP 3: PAYMENT

Online payment of BOC charges and fees through its accredited online payment facilities.

STEP 4: CLEARANCE AND RELEASE OF SHIPMENT

** FDA and BOC shall issue their respective Circular/Advisory for the detailed Step-by-Step process, consistent with the general steps stated herein.*

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