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**MASTER COPY**

10 February 2021

**CUSTOMS MEMORANDUM CIRCULAR**

No. 49-2021

**To: All Deputy Commissioners  
The Assistant Commissioner  
All Directors and Division Chiefs  
All District / Port Collectors  
And Others Concerned**

**SUBJECT: Requirements on the Importation of COVID-19 Vaccines**

Attached herein is the letter dated 03 February 2021 of Rolando Enrique D. Domingo, M.D., Director General, Food and Drug Administration (FDA), informing this Bureau of the needed requirements in the importation of COVID-19 Vaccines.

In the said letter, it was stated that per Center for Drug Regulation and Research, FDA, the importation of COVID-19 vaccines should only be based on FDA-MC No. 2013-032 providing that the importers be required only with FDA License to Operate (LTO) and valid Emergency Use Authorization (EUA) in lieu of the Certificate of Product Registration (CPR).

For information and guidance.

Please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt hereof.

  
**REY LEONARDO B. GUERRERO**

Commissioner

FEB 24 2021



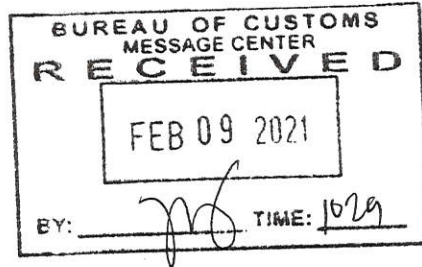
BOC-09-18747



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**

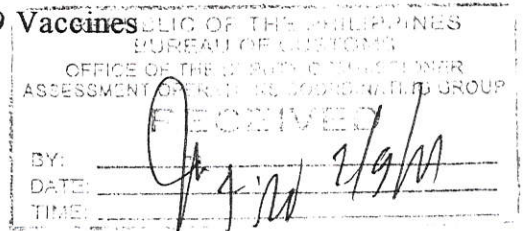


03 Feb 2021



**REY LEONARDO B. GUERRERO**  
*Commissioner*  
Bureau of Customs (BOC)  
G/F OCOM Bldg., 16<sup>th</sup> Street, South Harbor,  
Port Area, Manila

In Re: Needed Requirements in the Importation of Covid-19 Vaccines



Dear Commissioner Guerrero:

Greetings!

This letter is in relation to the needed requirements in the importation of Covid-19 Vaccine for immediate facilitation/release of the latter from the Philippine Ports.


As such, attached herein is the Memorandum from our Center for Drug Regulation and Research stating among others that the importation of COVID-19 vaccine be based on FDA-MC No. 2013-032 that the importers be required only with FDA License to Operate (LTO) and valid Emergency Use Authorization (EUA) in lieu of the Certificate of Product Registration.

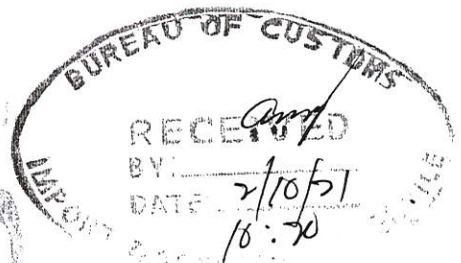
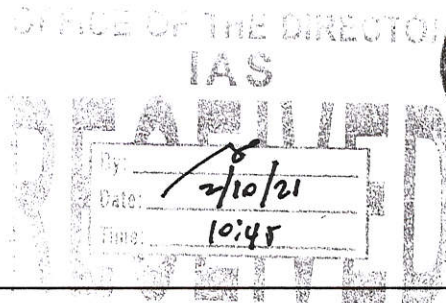
This information was already forwarded by our investigating team on 26 January 2021 to your Customs Intelligence and Investigation Service (CIIS) thru their viber group for incorporation to the BOC's Guidelines for frontliners in checking COVID-19 vaccine importations.

Should you have any other query, our FDA investigation team shall be ready to assist you.

Thank you for your usual cooperation and assistance.

Sincerely,

  
**ROLANDO ENRIQUE D. DOMINGO, M.D.**  
*Director General*  
Food and Drug Administration





Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**

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DATE : 21 January 2021

FOR : **ATTY. EMILIO L. POLIG, JR**  
Officer-in-Charge, Deputy Director General for Field Regulatory  
Operations Office

FROM : **JESUSA JOYCE N. CIRUNAY, RPh**  
Director IV, Center for Drug Regulation and Research

SUBJECT : **Request from Bureau of Customs (BOC) re: Guidelines on the  
needed requirements in the importation of COVID-19 Vaccines**

DTN : 20210119175210

This refers to your letter dated 18 January 2021 requesting this Office to respond to Bureau of Customs (BOC) on specific guidelines for COVID-19 Vaccines. We agree that the importation of COVID-19 vaccine be based on FDA-MC No. 2013-032 that the importers be required only with FDA License to Operate (LTO) and valid Emergency Use Authority (EUA) in lieu of the Certificate of Product Registration.

In this regard, please directly respond and coordinate to BOC on this matter considering the FDA Director General's answer to media queries that the FDA Field Inspectors will be present in all ports of entry for COVID-19 Vaccine importations.

Thank you.

cc: ODG







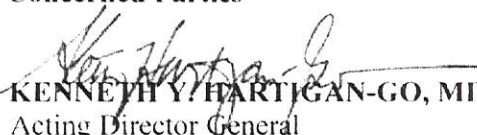
Republic of the Philippines  
Department of Health  
FOOD AND DRUG ADMINISTRATION

FDA 50

28 August 2013

FDA MEMORANDUM CIRCULAR  
No. 2013-032

TO : All FDA-Licensed Establishments, FDA Personnel, and Other Concerned Parties

FROM :  KENNETH Y. HARTIGAN-GO, MD  
Acting Director General

SUBJECT : REQUIREMENTS FOR THE IMMEDIATE RELEASE OF PRODUCTS COVERED BY THE FDA AT THE BUREAU OF CUSTOMS

Effective **September 15, 2013**, the Food and Drug Administration (FDA) will no longer issue letters of clearance or certifications for the Bureau of Customs (BOC) in order to release imported products and raw materials under the jurisdiction of the FDA.

The FDA letter of clearance or certification will no longer be a requirement or condition for the immediate release of finished products for as long as the importer is able to present or submit valid FDA License to Operate and valid Certificate of Product Registration or Notification. However, for raw materials, including ingredients and additives that are used for producing or processing finished products, the following shall be presented or submitted to the Bureau of Customs for immediate release:

- a) Food
- i. Raw materials, such as food ingredients and food additives, that are imported by FDA-licensed food establishments for their own use, the License to Operate shall be presented or submitted to the Bureau of Customs.
  - ii. Food ingredients and food additives, among other raw materials, that are intended for distribution or for sale, the License to Operate and the Certificate of Product Registration shall be presented or submitted to the Bureau of Customs.

b) Drugs

For raw materials used for drug manufacturing, only the License to Operate shall be presented or submitted to the Bureau of Customs.





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c) Cosmetics, and Household and Urban Hazardous Substances

For raw materials used in the manufacture of cosmetics and household and urban hazardous substances both the License to Operate and the Certificate of Notification/Registration are no longer required to be presented or submitted to the Bureau of Customs.

The BOC may verify or validate all establishments and products with FDA authorization using the FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)).

The following shall still require the FDA certification prior to release from the Bureau of Customs:

- a) All donated health products, which may need sampling and testing of products, or
- b) Products that have no market authorization yet, but will be used for exhibition, in trade promotion, or for clinical trial purposes, among others. Until such time that the FDA has not yet instituted an on-line application, payment, approval and release of certification, all applicants shall follow the existing procedure.

Application for import clearance or certification shall be received by FDA only until **September 14, 2013**.

For guidance and strict compliance.

