



FDA CIRCULAR
No. 2020-022-B

122 APR 2021

SUBJECT: AMENDMENT TO INCLUDE HEALTH PRODUCTS ASSOCIATED WITH THE CONDUCT OF COVID-19 VACCINATION FROM THE COVAX FACILITY/ WORLD HEALTH ORGANIZATION TO THE LIST OF IDENTIFIED DONATED HEALTH PRODUCTS UNDER THE SCOPE OF FDA CIRCULAR NO. 2020-022

The listing of health products enumerated in FDA Circular No. 2020-022, as amended by FDA Circular No. 2020-022-A, entitled "Reissuance of 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" is hereby further amended to read as follows:

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IV. SCOPE

This Circular implements the process of identification, notification, evaluation, review and monitoring and other regulatory or enforcement action of the 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, 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 from the COVAX Facility/World Health Organization, except vaccines and drugs.**

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For the information and guidance of the public.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

