



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA PRESS STATEMENT

20 January 2021

Donated COVID-19 Vaccines Require FDA Authorization

The Food and Drug Administration (FDA) clarifies that donated COVID-19 vaccines require FDA authorization in the form of Emergency Use Authorization (EUA) prior to use.

Entities which intend to donate vaccines to the government are required to coordinate with the Department of Health (DOH) which will facilitate the acceptance and processing of the donation. Thereafter, the proposed donation shall be evaluated. The DOH evaluates by considering the relevance of the donated product to the need of the beneficiaries, reliability of the source, shelf life and other relevant criteria.

If the COVID-19 vaccine for donation does not have an EUA from FDA, then the DOH has to apply for an EUA for the donated lot to ensure the safety, quality and efficacy of the product being donated. Only after authorization of the FDA may the DOH distribute the products to the intended beneficiaries.

Let it be stressed that the approval of the donated product does not mean free use thereof. FDA's authorization is limited to the donated lot and carries conditions for use depending on the nature of the donated product. DOH, as the donee, is mandated by the FDA to assume full responsibility on the use of the donated product. Thus, if DOH would accept donated COVID-19 vaccines and is granted an EUA, it shall assume full responsibility for said health product.

