Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

19 AUG 2021

FDA ADVISORY
No. 2021-2037

TO : **ALL MARKET AUTHORIZATION HOLDERS AND OTHER STAKEHOLDERS**

SUBJECT : **Clarification on the Coverage of Lot or Batch Release Certification Pursuant to Administrative Order No. 47-a s. 2001**

Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", states that it is the policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to protect the health of the Filipino people and help establish and maintain an effective health products regulatory system.

Further, Administrative Order (AO) No. 47-a s. 2001 entitled "Rules and Regulations on the Registration, including Approval, and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products" defines "Biologic" or "Biologic Product" as any attenuated or inactivated virus or bacteria, or sub-components attached to adjuvants, toxoids, hyperimmune serum and analogous products applicable to diagnosis, prevention, treatment or cure of disease or injuries to man, obtained or derived from living matter - animals, plants or microorganism, or parts thereof. It includes preparations primarily designed to develop a type of immunity or preparations that are concerned with immunity.

In order to streamline the regulatory processes and facilitate the access to medicinal products, the requirement of a Lot or Batch Release Certification is limited to **vaccines**, **toxoids** and **immunoglobulins** only.

The Lot or Batch Release Certification requirement on all Certificates of Product Registration of all drug products other than vaccines, toxoids and immunoglobulins shall be deemed no longer imposed.

For information and guidance of all concerned.

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