

FULL IMPLEMENTATION OF THE LOT OR BATCH RELEASE CERTIFICATION REQUIREMENT

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Read online (full-text search, related cases, audio case brief): <https://batas.org/library/25903bae1e4d/>

Pursuant to the provisions of Sec. IV, DOH A.O. No. 47-A, s. 2001 (Rules and Regulations on the Registrations, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products), it is hereby announced that effective immediately, all lots or batches of established, new and developmental biologic products, including vaccines, except UNICEF/WHO products, must first be certified by this Bureau prior to entry and/or release for sale in the Philippines.

For further details as to how the above can be accomplished, all interested parties are hereby advised to get in touch with the personnel handling such at the Laboratory Services Division.

For information and guidance of all concerned.

Adopted: 02 March 2005

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