

COLD CHAIN MANAGEMENT REQUIREMENTS

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Pursuant to the provisions of Republic Act No. 3720 otherwise known as Food, Drugs, Devices and Cosmetics Act, as amended by Executive Order No. 175, and in line with the objectives of Department of Health Administrative Order Nos. 56 s. 1989, 27 s. 2001 and 47-A s. 2001, the attached requirements [*] are hereby for information, guidance and strict compliance of all concerned.

All establishments and outlets applying for a license to manufacture, import, distribute or sell vaccines and other biological products are hereby directed to comply with the said requirements. This compliance will partly determine whether a certain establishments is capable to handle vaccines and biological products and shall be reflected in its License to Operate (LTO).

Existing establishments handling vaccines and other biological products are likewise directed to upgrade their Cold Chain Management capabilities as provided for in this issuance. Renewal/revalidation of their LTOs will be partly based on this.

For purposes of identification, a phrase “Capable to handle vaccine and biological products” shall be printed prominently in the LTOs of concerned establishments and shall serve as a major prerequisite once their products are being applied for registration.

This circular takes effect immediately.

Adopted: 01 Feb. 2007

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Director IV

[*] Text Available at Office of the National Administrative Register, U.P. Law Complex, Diliman, Quezon City.

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