GUIDELINES FOR LICENSING OF WHOLESALERS, IMPORTERS, EXPORTERS AND DISTRIBUTORS OF REGULATED PRODUCTS

PREAMBLE

In pursuance of Sections122, 130,131 and 132 of the Public Health Act, 2012 (Act 851) these guidelines are hereby made to provide for the proper importation, exportation, storage, handling, transportation and distribution of regulated products so as to ensure that these products maintain their integrity throughout their shelf lives.

SCOPE

This guideline applies to any person, partnership, corporation, or business firm engaging in the importation, exportation, storage, transportation and wholesale distribution of regulated products.

INTERPRETATIONS

In this guideline:

Regulated product means drugs, herbal medicines, cosmetics, household chemicals and medical devices

Authorized officer means a Regulatory Officer of the FDA.

Authorized Personnel means any person with a background in the sciences (As defined in the Guidelines for Selection of Authorized Persons in the Pharmaceutical industry.)

LICENSING REQUIREMENT

Every distributor or importer who engages in distributions of regulated products in commerce must be licensed by the Food and Drugs Authority (FDA) in accordance with the Public Health Law, 2012, before engaging in distributions of regulated products.

MINIMUM REQUIRED INFORMATION FOR LICENSURE

(A) The FDA shall require the following minimum information from each wholesale distributor or importer, exporter as part of the license and as part of any renewal of such license:

(1) The name, full business address, location/Site address and telephone numbers (including mobile numbers) of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of regulated products.

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director and corporate names.

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(B) The FDA may provide for a single license for a business entity operating more than one facility within the country, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within the country when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(C) Changes in any information in paragraph **(A)** of this section shall be submitted to the FDA as required.

MINIMUM QUALIFICATIONS.

(A) The FDA shall consider, as a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution, exportation and importation of regulated products:

(1) Any convictions of the applicant under any laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under local laws;

(3) The applicant's past experience in the manufacture, importation, exportation or distribution of regulated products, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by the FDA of any license currently or previously held by the applicant for the manufacture, importation or distribution of any regulated products, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the FDA those records required under this section; and

(8) Any other factors or qualifications the FDA considers relevant to and consistent with the public health and safety.

(B) The FDA shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest

The FDA shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with requirements.

VIOLATIONS AND PENALTIES

(A) The Public Health Law provides for the suspension or revocation of licenses upon conviction on violations of the laws or regulations, and may provide for fines, imprisonment or administrative charges.

(B) The Public Health Law shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF REGULATED PRODUCTS

The following are minimum requirements for the storage and handling of regulated products and for the establishment and maintenance of distribution records by wholesalers and distributors and their officers, agents, representatives, and employees:

(A) *Facilities.*

All facilities at which regulated products are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of products that are expired, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(B) ***Security.***

(1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where products are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(C) ***Storage.***

Drugs and other products shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or products, or with requirements in the current edition of an official compendium, such as in Schedule four of the Public Health Law. (**Ref: Guidelines for Good Distribution Practices in the Pharmaceutical Industry**)

(1) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of products.

(D) ***Examination of materials.***

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated products or products that are otherwise

unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the products and to ensure that there is no delivery of products that have been damaged in storage or held under improper conditions.

(E) ***Returned, damaged, and expired products.***

(1) Products that are expired damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other products until they are destroyed or returned to their supplier.

(2) Any product whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other products until they are either destroyed or returned to the supplier.

(3) If the conditions under which a product has been returned cast doubt on its safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on the its safety, identity, strength, quality, or purity, the wholesaler or distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(F) ***Recordkeeping.***

(1) Wholesalers and distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of products. These records shall include the following information:

> (i) The source of the products, including the name and principal address of the seller or transferor, and the address of the location from which the products were shipped;
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> (ii) The identity and quantity of the product received and distributed or disposed of; and
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> (iii) The dates of receipt and distribution or other disposition of the product.

(2) Inventories and records shall be made available for inspection and photocopying by authorized officers for a period of 3 years after the date of their creation.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by authorized officers.

(G) ***Written policies and procedures.***

Wholesalers and distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of products, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesalers and distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the first-to-expire or first-in first-out approved stock of a product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of products. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drugs Authority;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective products from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesalers and distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local or national emergency.

(4) A procedure to ensure that any expired product shall be segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of expired products. This documentation shall be maintained for 2 years after disposition of the expired products.

(H) ***Responsible persons.***

Wholesalers and distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale and distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(I) ***Compliance with FDA Requirements.***

Wholesalers and distributors shall operate in compliance with the Public Health Law and applicable guidelines and regulations.

(1) Wholesalers and distributors shall permit authorized officers to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by

law.

PROCEDURE FOR LICENSING

Applicants shall submit a written application to the FDA together with all relevant documentation. The applicant shall be made to pay a prescribed fee. The FDA shall inspect the premises to ascertain the suitability of the premises prior to the issuance of a license.