FOOD AND DRUGS AUTHORITY

GUIDELINE FOR LICENSING OF PREMISES FOR THE STORAGE AND DISTRIBUTION OF COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES

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ACKNOWLEDGEMENT

It is acknowledged that in the development of this Guideline, reference was made to the following sources:

- ISO 22716:2007 (Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices)
- Public Health Act, 2012 (Act 851)
- WHO Technical Report Series, No. 957, 2010, Annex 5, WHO Good Distribution Practices for Pharmaceutical Products
- WHO Technical Report Series, No. 908, 2003 Annex 9, Guide to Good Storage Practices for Pharmaceuticals

TABLE OF CONTENTS **PAGE NO.**

1.0 INTRODUCTION

In pursuance of Sections 122(1), 130, 131 and 148 of the Public Health Act, 2012 (Act 851), this Guideline is hereby made to provide information on the requirements for the registration and licensing of premises or facilities for the storage and distribution of cosmetics and household chemical substances in Ghana and also for the upkeep of already licensed storage facilities. This includes information on Good Storage Practice/Good Distribution Practice (GSP/GDP) requirements for cosmetics and household chemical substances.

This Guideline applies to all person(s) that engage in the importation, exportation, storage, transportation, wholesale and distribution of cosmetics and household chemical substances in Ghana. In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), these person(s) shall not offer for sale, sell, supply or store cosmetics and household chemical substances except in premises registered and licensed by the Food and Drugs Authority (FDA) for that purpose. In addition, in accordance with Section 118(1), cosmetics and household chemical substances imported, exported, sold, supplied, exhibited for sale and distributed by these person(s) are required to be registered with the Authority.

Premises for the storage, wholesale and distribution of cosmetics and household chemical substances shall be subjected to pre-licensing and post-licensing GSP/GDP inspection in accordance with the requirements of this Guideline. The inspection will be risk-based, and will be informed by factors such as product and process risk, compliance history, risk associated with the use of the product, and relevant recalls carried out.

Improper storage and distribution of cosmetics and household chemical substances along the supply chain may lead to undesirable, and in some cases extremely serious consequences.

The purpose of the GSP/GDP inspection therefore is to verify that cosmetics and household chemical substances imported, exported, stored, transported, wholesaled and distributed consistently meet applicable regulatory requirements. The GSP/GDP inspection observations, if found to be satisfactory, will guide the Authority in its decision to issue a new licence or renew an existing licence in accordance with Section 131 of the Act.

Applicants are advised to observe the provisions of this Guideline before submitting an application for registration and subsequent licensing of its premises for the storage and distribution of cosmetics and household chemical substances.

This Guideline is hereby promulgated for information, guidance and strict adherence by all concerned.

2.0 GLOSSARY

In this Guideline, unless the context otherwise requires, the following terms have the assigned meanings:

2.1 Authority: Food and Drugs Authority (FDA).

2.2 Authorized officer: A Regulatory Officer of the Authority.

2.3 Complaint: External information claiming a product does not meet defined acceptance criteria.

2.4 Contamination: The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a finished product during production, sampling, packaging or repackaging, storage or transport.

2.5 Cosmetic: A substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.

2.6 Counterfeit product: A product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, with the wrong ingredients, with an incorrect quantity of ingredients or with fake packaging.

2.7 Distribution: The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products.

2.8 Distributor: Legal person in the supply chain who makes a product available on the market up until the point of putting into trade.

2.9 Entity: Any legal person, engaging in the importation, exportation, storage, transportation and wholesale distribution of cosmetics and household chemical substances. .

2.10 Expiry date: The date given on the individual container (usually on the label) of product up to and including the period within which the product is expected to remain within specifications, if stored correctly.

2.11 Export: To take or cause to be taken out of the Republic.

2.12 First expiry/First out (FEFO): A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date.

2.13 Good Distribution Practice (GDP): That part of quality assurance that ensures that the quality of a product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, substandard, falsified or misbranded products.

2.14 Good Storage Practices (GSP): That part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.

2.15 Household chemical substances: This refers to a substance or mixture of substances packaged for use in a domestic or office setting as a germicide, an antiseptic, a disinfectant, a pesticide, an insecticide, a rodenticide, a vermicide, or a detergent; or any other substance or mixture of substances declared by the Minister, after consultation with the Authority, to be a chemical substance.

2.16 Import: Bring into the Republic.

2.17 Importer: A person who brings into the Republic a cosmetic or household chemical substance.

2.18 Labelling: Process of identifying a product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

2.19 Manufacturer: A company that carries out operations such as production, packaging, repackaging, labelling and relabeling of cosmetics and household chemicals.

2.20 Premises: Any location that is used for activities dealing with cosmetics and household chemicals including manufacture, storage and distribution.

2.21 Recall: A process for withdrawing or removing a product from the distribution chain because of defects in the product, consumer complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

2.22 **Storage:** The storing of products up to their point of use.

2.23 **Supplier:** An entity providing cosmetics or household chemical substances on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where possible, suppliers should be authorized by a competent authority.

2.24 **Wholesale:** Supplying cosmetics or household chemicals to a person or entity who obtains the product for the purposes of supplying it further to another person or entity.

3.0 REQUIREMENTS

3.1 APPLICATION REQUIREMENTS

3.1.1 New Applications

3.1.1.1 An application to register and license a new facility for the storage and distribution of cosmetics and household chemical substances shall be made in writing by submitting a completed application form with a cover letter addressed to:

The Chief Executive Officer
Food and Drugs Authority
GA-237-7316
Accra

3.1.1.2 The completed application form (FDA/MCH/MID/APS-LCH/2019/04) shall be dated, signed and stamped by the applicant and shall provide the following minimum information as part of the licence acquisition:

(a) The name, full business address, location/site address and telephone numbers (including mobile telephone numbers) of the applicant.
(b) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of cosmetics and household chemical substances. If the storage facility is owned by a third party other than the owner of the business, the details of the third party, should also be provided.
(c) The type of ownership of the premise (i.e. whether applicant-owned or third-party owned) and the name(s) of owner(s)
(d) The type of business operation (i.e., partnership, corporation, or sole proprietorship); and the name(s) of the partner(s)/director(s)/proprietor(s) of the applicant.

3.1.1.3 The completed application form shall be accompanied by:

(a) Non-refundable application fee as specified in the Authority's Fee Schedule.
(b) Certified true copies of Certificate of Incorporation and Certificate to Commence Business from Registrar General's Department

3.1.1.4 In situations where the storage facility is more than one, a separate application is required for each premise, except where a group of buildings on one or more sites are engaged in storing and distributing the same kind of product under the same direct storage and distribution management.

3.1.1.5 The Authority shall consider, as a minimum, the following factors in reviewing the qualifications of applicants:

(a) Any convictions of the applicant relating to FDA-regulated products.

(b) The applicant's history of regulatory compliance in the storage and distribution of FDA-regulated products.
(c) The applicant has provided the Authority with false or fraudulent information or material in respect of its application for FDA-regulated products.
(d) The applicant's licence has been suspended or revoked by the Authority for violation of any FDA law, and
(e) Any other requirements the Authority may from time to time prescribe.

3.1.1.6 The Authority may approve, defer or refuse an application following assessment including GSP/GDP inspection findings which shall be duly communicated to the applicant.

3.1.1.7 A licence issued under this Guideline shall be valid for one year and shall be renewable.

3.1.1.8 The Authority shall exercise the right to cancel or suspend a licence in accordance with the law.

3.1.1.9 An applicant shall submit any and all changes in their application information to the Authority prior to amending or changing its existing records or information.

3.1.2 Renewal Applications

3.1.2.1 The registration and licensing of the premises shall be renewed annually.

3.1.2.2 An application for renewal of the registration of premises shall be made at least 3 months before the expiry of the existing licence by submitting with a cover letter the following:
(a) Duly completed application form (FDA/MCH/MID/APS-LMD/2019/04).
(b) Non-refundable application fee in accordance with the FDA fee schedule.

3.1.2.3 The applicant's compliance with GSP/GDP shall be a key determinant to the renewal of the registration and licensing of the premises.

3.2 GSP/GDP REQUIREMENTS

Entities engaged in the importation, storage, wholesale, distribution, transportation, and exportation of cosmetics and household chemical substances would have to comply with the basic elements of good storage/distribution practice listed below:

(1) Quality system
(2) Management and Personnel
(3) Premises and Storage Areas
(4) Management of Products
(5) Distribution, Dispatch and Transport
(6) After Sales Obligations
(7) Documentation and Records
(8) Disposal of Products

3.2.1 Quality System

3.2.1.1 Quality management system: The entity is required to put in place an effective quality system that provides assurance that:

(a) Only cosmetics and household chemical substances which comply with applicable regulatory and customer requirements are distributed
(b) Non-compliant, defective or unsuitable medical devices can be detected
(c) A traceability system is established, implemented and maintained
(d) Non-conformances and the introduction of changes are controlled.

3.2.1.2 *Outsourced activities:* Where an entity outsources any activity that may affect the quality of cosmetics and household chemical substances being stored and distributed, the entity shall ensure control over such processes to ensure that the outsourced activities conform to specified requirements. Technical agreements should be in place for all outsourced activities relating to storage and distribution. The technical agreements should at least describe the roles and responsibilities of both parties including details on transportation arrangements, receipt of goods, batch release arrangements, customer approval, documentation, recalls, returns, customer complaints, suspected falsified cosmetics and household chemical substances, and management of deviations and changes.

3.2.1.2 *Rental of storage premise*: Where an entity rents a premise for the purposes of storage and distribution, the entity shall ensure that the activities in the rented premises conform to specified requirements contained in this Guideline.

3.2.2 Management and Personnel

3.2.2.1 *Organizational chart (reporting structures and role profiles)*: The organizational structure should be defined such that the organization and functioning of the staff of the entity is understood. It should be appropriate for the size of the entity and the diversity of products stored and distributed. The responsibilities and authorities within the organization should be defined, documented and communicated. Additionally, the entity shall establish the interrelation between all personnel who manage, perform and verify work that affects storage and distribution of cosmetics and household chemical substances and should ensure the independence and authority to perform these tasks. The implementation of GSP/GDP should be the responsibility of management and should require the participation and commitment of all personnel within the entity.

3.2.2.2 *Personnel Adequacy, Competency and Training*: There should be sufficient trained personnel with the appropriate skills and experience to carry out all necessary tasks with respect to the storage and distribution of cosmetics and household chemical substances. Training should include but not be limited to the following:

- Defined responsibilities and roles
- Product storage requirements
- Labelling
- Reporting of non-compliances

- Segregation of storage areas to minimize the risk of mix-ups
- Recall/withdrawal procedures
- Complaints procedures
- Product security
- Product identification
- Detection of counterfeits and the prevention of counterfeits entering the supply chain.

The effectiveness of trainings or other actions taken should be evaluated and appropriate records on education, training, skills and experience should be kept.

3.2.2.3 *Personnel Hygiene and health:* All members of staff should observe high levels of personal hygiene and sanitation. This should include the wearing of suitable protective or working garments appropriate for the activities they perform, particularly for personnel employed in storage areas. In addition steps should be taken to ensure, as far as is practicable, that any person affected by an apparent illness or having open lesions on the exposed body surface should be excluded from direct contact with product until the condition is corrected or determined by medical personnel that the quality of products will not be compromised.

3.2.2.4 *Internal audit:* Management shall ensure that, the entity conducts internal audits at planned intervals to determine whether the GSP/GDP requirements detailed in this guideline are implemented effectively. An effective procedure for internal audits which provides a minimum of the following should therefore be followed:

- Defined frequency of conducting internal audits
- Selection of inspectors should ensure that individuals do not inspect/audit their own work.
- All observations made during the internal audit are evaluated and shared with appropriate responsible personnel.
- Internal audit follow-up confirms the satisfactory completion or implementation of corrective actions

3.2.3 Premises and Storage Areas

3.2.3.1 *Receiving and dispatch bay:* Receiving and dispatch bays should protect products from the weather. In addition, reception areas should be designed and equipped to allow containers of incoming products to be cleaned, if necessary, before storage.

3.2.3.2 *Accessibility to Storage Areas:* Precautions must be taken to prevent unauthorized persons from entering storage areas.

3.2.3.3 *Size and Capacity of Storage Areas:* Storage areas should generally permit organized storage. It should be of sufficient capacity to allow the orderly arrangement of all category of products under storage (i.e products in good

condition, returned or recalled products as well as quarantined products). The storage area for the various categories of products should therefore be clearly defined and demarcated

3.2.3.4 *Ventilation and Illumination:* Storage areas should provide adequate ventilation and lighting to enable all operations to be carried out accurately and safely. Lighting should be installed in a manner to ensure containment of any debris from potential breakage.

3.2.3.5 *Cleaning and sanitation:* Storage areas should be clean, and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination. Wastes should be disposed of in a timely and sanitary manner.

3.2.3.6 *Pest control*: Premises should be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin. There should be a pest control programme appropriate for the premises to identify and prevent pest infestation. Furthermore, measures should be taken to control the exterior of the premises to prevent attracting or harbouring pests. Any pest-control agents used should be safe, and there should be no risk of contamination of the products. A bait map should show the locations of all pest control monitoring stations. Any recommendations made by a pest control service provider should be implemented and recorded. If recommendations are not implemented, an explanation should be recorded. All pest control records should be approved by the entity and maintained.

3.2.4 Management of products

3.2.4.1 Receipt of products: The entity shall establish and implement inspection or other activities necessary to ensure that products received meet specified requirements. Records of products received should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, batch number and the expiry date.

3.2.4.2 *Product Segregation:* Where an entity's storage facility has capacity to hold different regulated products, the owner shall ensure that markedly distinct, separate or defined areas are provided for the different regulated products.

3.2.4.3 *Packing and arrangements of products*: Generally, products should be handled and stored in such a manner as to prevent contamination and mix-ups. Products received should be suitably packed on pallets, racks, shelves and other packing aid which should be kept in a good state of cleanliness and repair. Products should be stored off the floor and suitably spaced (preferably not against the wall) to permit cleaning and inspection. Containers of products should be closed.

3.2.4.4 *Storage of products and monitoring of storage conditions:* Storage areas should be designed or adapted to ensure good storage conditions.. Fundamentally,

they should be clean and dry and maintained within acceptable temperature limits.

Generally, products should be stored and handled in a manner appropriate to their characteristics. For instance, substances presenting special risks of fire and explosion (e. g combustible liquids and solids, pressurized gases or aerosols) should be stored in a dedicated area that is subject to appropriate additional safety and security measures.

Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, checked, monitored and recorded. The equipment used for monitoring such as thermometers should be appropriately maintained, kept in a good state of repair and calibrated at defined intervals. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

3.2.4.5 *Stock rotation:* the entity shall establish a system to ensure stock rotation. The "first expired/first out" (FEFO) principle should be followed. Except in special circumstances such as expiry, stock rotation should ensure that the oldest released stock is used first (FIFO-first-in/first-out). Cosmetics and household substances beyond their expiry date or shelf life shall be segregated from usable stock and should be clearly identified as such. All stock should be checked regularly for obsolete and outdated products. All due precautions should be observed to prevent the issue of outdated products.

3.2.4.6 *Stock reconciliation:* Periodic stock reconciliation should be performed by comparing the actual and recorded stock. All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue and corrective action taken.

3.2.4.7 *Damaged packages and broken/damaged products*: Products with damaged packages should not be issued unless the quality of the product has been shown to be unaffected. Where possible, this should be brought to the attention of the person responsible for quality control. Any action taken should be documented. Broken or damaged items should be withdrawn from usable stock and separated.

3.2.4.8 *Returned products:* Returns should be identified in an appropriate way and stored in defined areas. Returns need to be evaluated against established criteria to determine their disposition. Release should be given before placing returns on the market again. Measures should be established to distinguish returned products to avoid their inadvertent redistribution if unreleased.

3.2.4.9 *Substandard/falsified products:* Products stored and distributed to the public shall not be substandard, falsified or counterfeit products. Substandard/falsified products found in the distribution chain should be kept apart from other products to avoid any confusion. They should be clearly labelled as "not for sale". The

sale and distribution of a suspected falsified/counterfeit product should be suspended and the authority notified without delay. Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

3.2.4.10 *Rejected products:* When products are quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance***.***

3.2.5 Distribution, Dispatch and Transport

3.2.5.1 *Transport Storage Conditions:* Products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained. In addition, the outside container should offer adequate protection from all external influences and should be indelibly and clearly labelled during transport.

3.2.5.2 *Dispatch records:* Records for dispatch should be retained, stating at least the date of dispatch, the customer's name and address, the product description, batch number, and quantity. For temperature sensitive products, the transport storage conditions should also be recorded during transport and dispatch.

3.2.5.3 *Accessibility of records:* All records on dispatch and transport should be readily accessible and available on request.

3.2.6 After-sales obligations

3.2.6.1 *Distribution Records/ Product Traceability:* Cosmetics and household chemical substances shall be appropriately identified and the entity shall keep and maintain records on its distribution to allow for traceability. These records should include amongst others batch number, manufacturing date, expiry date, name and address of the consignee, date of issue and any other records that will facilitate traceability.

3.2.6.2 *Complaint handling:* All complaints to the entity should be reviewed, investigated and followed up on, as appropriate. The entity shall therefore establish a documented procedure for handling customer complaints. Records of the complaint, investigation and any subsequent actions taken shall be maintained.

3.2.6.3 *Adverse Event reporting*: Any complaint or reports of adverse event that meets the regulatory reporting criteria received by the organization shall be reported to the regulatory authority as well as to the manufacturer.

3.2.6.4 *Recall:* The entity shall establish documented procedures for the recall of cosmetics and household chemical substances that do not meet regulatory requirements. The recall procedure in place should be robust enough to enable the swift and effective recall from the marketplace of defective and/or potentially harmful cosmetics and household chemical substances. When a product recall decision is made, appropriate steps should be taken to complete the recall as required and to implement corrective action. All recalled products shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal or otherwise.

3.2.6.5 *Advertising (representation)*: Unapproved advertisement of product is prohibited. The entity shall therefore take steps to ensure that any products to be advertised are duly registered with the Authority and the advertisement is vetted and approved by the Authority.

3.2.7 Documentation and Records

3.2.7.1 *Procedures and Records*: Written instructions, procedures and corresponding records should be available to support activities carried out in the facility. This should include but not be limited to the following:

- Receipt, Storage, Issue and Distribution of Products
- Monitoring of Storage conditions
- Stock rotation and control
- Handling of Outdated/Expired stocks
- Returned or recalled goods
- Cleaning
- Pest control
- Complaint handling
- Training of Personnel
- Internal audit
- Identification and handling of unwholesome and counterfeit Products

3.2.7.2 *Control of Documents and Records:* Documents, including SOPs should be written in a legible and comprehensive way, approved, signed by authorized persons before being used and should be made accessible to appropriate personnel. The corresponding records should equally be legible and comprehensive.

3.2.7.3 *Records Retention:* Records should be retained for a period equal to the shelf-life of the product, where applicable, plus 1 year. Where the records are generated and kept in electronic form, back-ups should be maintained to prevent any accidental data loss.

3.2.8 Disposal of Products

3.2.7.1 All cosmetics and household chemicals that are rejected in-house, rejected when received as a return from a customer, expired, unwanted or recalled stock should, if instructed accordingly, be destroyed in an appropriate and timely manner and in accordance with waste legislation.

3.2.7.2 A documented procedure for safe disposal should therefore be developed. The decision to dispose of products and inventory of such products should be documented.

3.2.7.3 In accordance with Section 132(2) & (3), the Authority shall supervise the safe disposal process at a fee. Accordingly, a person shall not dispose of an unwholesome regulated product without the supervision of the Authority.

3.2.7.4 If the unwanted products have not been immediately sent for disposal, they shall be kept in a clearly segregated area and identified so that they will not be sold inadvertently or contaminate other products. Records of the disposal including certificates shall be maintained.

3.3 CLASSIFICATION OF INSPECTION FINDINGS / NON-COMFORMITIES

3.3.1 Non-conformities

Non-conformities identified, following an inspection may be classified as major or minor and they have to be corrected. These shall be communicated to the entity and a corrective and preventive action to address them would be required of the company inspected.

3.3.1.1 *Major non-conformity:* A major non-conformity is a serious deficiency that could adversely affect product quality (i.e. specification). It could also be a single infraction that by itself constitutes evidence of persistent failure. A number of observations that individually are of small importance whose frequency indicates a serious deficiency can also be classified as major non-conformity.

3.3.1.2 *Minor non*-conformity: A minor non-conformity is an isolated instance of failure to conform with a specified requirement that does not have an effect on product quality.

3.3.2 Other Observations

Inspection observations that are not non-conformities per se but worth noting may be expressed as “Opportunity for improvement” or “Concern”.

3.3.2.1 *Opportunity for Improvement:* Inspection findings that appear to be undesirable but cannot be cited as a non-conformity are described as “Opportunity for improvement”. Corrective action is not required.

3.3.2.2 *Concern:* An inspection or audit finding is said to be of “Concern” in situations in which there is no information at the time of the inspection to determine if a non-conformity exists. The concern shall be noted in the inspection report for further regulatory action.

3.4 STAKEHOLDER TRAINING

The Authority will periodically conduct appropriate stakeholder training for importers and distributors to enhance their level of compliance.

4.0 TIMELINES

4.1 Conducting the inspection

Barring unforeseen circumstances, inspection of the storage facility will be carried out within 90 days upon receipt of application.

4.2 Unannounced Inspections

Despite existing protocols with respect to planned inspections, the Authority shall, when it deems it necessary, conduct unannounced inspections for the purposes of ensuring that the importer/distributor's operations conform to applicable law.

4.3 Communication of Inspection findings

The inspection findings shall initially be communicated to the importer/distributor during the closing meeting of the inspection and an observation form shall be issued. This will be followed by a formal inspection observation letter within 21 days after the inspection.

4.4 Response to nonconformities

The importer/distributor is required to formally respond to the deficiencies/nonconformities identified in the inspection report as officially communicated within a specified timeframe (15 working days on receipt of the formal inspection findings letter).

4.5 Issuing of licences

4.5.1 After all corrections and corrective actions have been submitted to the Authority, evaluated and found to be satisfactory, a licence would be issued to the inspected company to close out the inspection.

4.5.2 The licence will only be valid for the period stated on the licence, provided there will be no quality and safety issues on the product or product category stored and distributed at the site inspected.

4.5.3 For a previously inspected existing importer/distributor applying for a licence, the licence will be issued within 30 days upon payment of the required application fee and satisfactory evaluation of the importer's/distributor's previous inspection Corrective and Preventive Action (CAPA).

5.0 ADDITIONAL NOTE

The manufacturing facility from where cosmetics and household chemical substances are produced and subsequently marketed in Ghana shall be subjected to Good Manufacturing Practice (GMP) inspection in accordance with the requirements of the current ISO 22716. Applicants should refer to the Guideline for Licensing of Premises for Manufacturing Cosmetics and Household Chemical Substances **(FDA/MCH/MID/GL-CH-GMP 2019/02).**