FOOD AND DRUGS AUTHORITY

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Governing Board / CEO, Food and Drugs Authority

GUIDELINE ON LICENSING OF MEDICAL PRODUCTS STORAGE FACILITIES

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This guideline replaces 'Guidelines for Licensing Storage Facilities of Wholesalers and Distributors of Pharmaceutical Products, Herbal Medicines and Food Supplements (FDA/DRID/DID/GL-WDL/2019)'

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
15/03/2019	01	Initial Issue
26/07/2019	02	Inclusion of sections 3.7, 3.8, & 3.10
29/08/2024	**03**	**i. General review of document to align with the new organogram and QMS requirements.** **ii. WHO Landing Page for Technical Report Series (TRS) in Acknowledgements** **iii. 3.1.1.10 / 3..1.2.4 Submission of application to any of the FDA Regional offices (Annex 5)** **iv. Inclusion of regional office application, timelines and feedback mechanisms (4.5.2, 4.5.3)** **v. Inclusion of Variation (5.0)** **vi. Appendix 5 - List of Regional Offices**

Acknowledgements

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

- Public Health Act, 2012 (Act 851)
- **All WHO Guidelines related to Good Distribution Practices (GDP) and Good Storage Practices (GSP) Practices for Medical Products**
  WHO Technical Report Series, https://www.who.int/publications/who-guidelines

Executive Summary

This document is a guideline that prescribes how applications for the licensing of medical product storage facilities shall be made to the Food and Drugs Authority Ghana.

The guideline highlights the format of the application and the processes involved leading to licensing of a storage facility, including the facility inspection and the timelines for each activity in the licensing process.

The objective of this guideline is to serve as a guide to applicants, increase transparency in the FDA's operations and build confidence and accountability in the licensing structure via public availability of information on the licensing process.

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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 Medical Products in Ghana and also for the upkeep of already licensed storage facilities. This includes information on Good Storage and Distribution Practice (GSDP) requirements for Medical Products.

This Guideline applies to all person(s) that engage in the importation, exportation, storage, transportation, wholesale and distribution of Medical Products/ 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 Medical Products 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), Medical Products substances imported, exported, sold, supplied, exhibited for sale and distributed by these people(s) are required to be registered with the Authority.

Premises for the storage, wholesale and distribution of Medical Products 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 Medical Products 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 Medical Products/ 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 license or renew an existing license 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 Medical Products substances.

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

1.1 Legal Basis

1.1.1 The following sections of the Public Health Act 2012, Act 851 mandates the Authority to carry out inspections and licensing of manufacturing facilities to achieve the desired safety, quality, and efficacy of the products for human and animal use regulated by the Authority.

- Section 130: Registration of premises
- Section 131: Licenses and permits.

1.1.2 Section 148 of The Public Health Act, 2012, Act 851 further mandates the Authority to issue guidelines and codes of practice in connection with products regulated by the Authority to persons in the industry and are required to comply. It is based on this legal provision that this guideline has been developed.

1.1.3 In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), the supply or storage of drugs/ medical products shall not be carried out except in premises registered (licensed) by the Food and Drugs Authority (FDA) for that purpose.

1.1.4 Pursuant to Section 118(1), drugs/ medical products imported, exported, distributed, sold, supplied by business entities are required to be registered with the Authority before placing them on the Ghanaian market.

1.2 Scope

1.2.1 This Guideline applies to all business entities duly registered by the Registrar-General Department with intention to establish a medical product storage facility in Ghana.

1.2.2 This guideline applies to facilities that store and distribute drugs or pharmaceutical or nutraceutical dosage forms or any medical products. This includes oral tablets., oral liquids, suppositories, topical preparations, parenterals, inhalers, patches, medical devices etc.

1.2.3 Storage and Distribution entities will be inspected to confirm compliance to the Authority's guideline on Good Storage and Distribution Practice (GSDP) requirements for medical products and other applicable regulatory requirements for drugs.

1.2.4 Applicants are therefore advised to observe the provisions of this Guideline before applying for licensing or re-licensing of their premise(s) for the storage and distribution of drugs/ medical products.

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 Counterfeit product: A product which is deliberately and fraudulently mislabeled 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.

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

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

2.8 Entity: Any legal person, engaging in the importation, exportation, storage, transportation and wholesale distribution of Medical Products.

2.9 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.

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

2.11 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.

2.12 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.

2.13 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.

2.14 Import: Bring into the Republic.

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

2.16 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.

2.17 Manufacturer: A company that carries out operations such as production, packaging, repackaging, labelling and relabeling of Medical Products.

2.18 Medical Product: A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action

2.19 Premises: Any location that is used for activities dealing with Medical Products including manufacture, storage and distribution.

2.20 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.

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

2.22 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.

2.23 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.

2.24 LIST OF ABBREVIATIONS

CAPA : Corrective Action and Preventive Action
EPA : Environmental Protection Agency
GDP : Good Distribution Practices
GSP : Good Storage Practices
GSDP : Good Storage and Distribution Practices
FDA : Food and Drugs Authority
WDL : Wholesale Distributors License
GL : Guidelines
ID : Inspectorate Directorate
SFD : Storage Facility Department
TOD : Technical Operations Division
Vmaj : Major Variation
Vmin : Minor Variation
QMS : Quality Management System

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 Medical Products 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 shall be dated, signed and stamped by the applicant and shall provide the following minimum information as part of the license 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 Medical Products. 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 license 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 license 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 license 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.

3.1.1.10 An application for licensing of a storage facility for medical products can be submitted at any of the FDA offices (Appendix 5)

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 license by submitting with a cover letter the following:
(a) Duly completed application form
(b) Non-refundable application fee in accordance with the FDA fee schedule.

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

3.1.2.4 A Renewal application for licensing of a storage facility for medical products shall be submitted to the FDA offices (Appendix 5)

3.2 GSP/GDP/ GSDP REQUIREMENTS

Guideline on Inspection of Medical Products Storage Facilities (FDA/SFD/GDL - 01)

3.3 CLASSIFICATION OF INSPECTION FINDINGS / NON-CNMFORMITIES

3.3.1 Observations/ Non-conformities

Non-conformities identified, following an inspection may be classified as critical, major or other and they have to be addressed. 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 *Other*/ *Minor non*-conformity: An other non-conformity is an isolated instance of failure to conform with a specified requirement that does not have a direct effect on product quality.

3.3.1.1 *Critical non-conformity:* A non-conformity is a critical deficiency that have existential risk/ severe deviation from established standards or regulations that poses a significant risk to safety, quality, or compliance. This type of non-conformity often requires immediate corrective action to prevent harm or further violation

3.3.2 Observations / Opportunity for improvement

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 nonconformity 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 licenses

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

4.5.2 For Regional Offices, completed application documents, along with inspection reports and CAPA (where applicable), shall be submitted to the Head Office.

4.5.3 For applications satisfactory a license shall be issued within ten (10) working days.

For unsatisfactory applications, feedback will be provided to the Regional Office within five (5) working days for communication to the respective applicants.

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

4.5.5 For a previously inspected existing importer/distributor applying for a license, the license 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 VARIATION

5.1 For any post-license variation, including changes to location, addition or decommissioning of equipment, or extension of facilities, the FDA must be notified in writing of these modifications.

5.2 The FDA will then review and respond to the variation application as appropriate. Each information on any variation to the FDA Ghana shall be accompanied by the requisite documentations as indicated in Annex 1 of this guideline

5.3 Post-license variation applications must be submitted to the authority through the regional offices where the facility was inspected and licensed.

5.4 For post license variation applications, the authority will respond to the variation application within 30 days upon receipt of application.

6. SANCTIONS

6.1 Cancellation / Suspension / Withdrawal /Revocation of licenses

6.1.1 The Authority shall cancel, suspend, or withdraw a licensure of a facility if.

(a) The facility contravenes GSDP requirements.
(b) Any of the conditions under which the license was issued no longer exist.
(c) The information on which the approval was given is later found to be false.
(d) The circumstances under which the approval was given no longer exist.

6.1.2 Where the licensure is suspended, withdrawn, or cancelled, the Authority shall issue a notice to the management of the facility.

6.1.3 The Authority shall take steps to ensure that the storage facility is stopped from storage until otherwise decided by the Authority. Measures towards enforcing this may include the publication of the FDA's action on its website and other relevant media.

6.2 Penalties

6.2.1 The Authority shall impose an administrative fine in accordance with the approved fees and charges Act applicable to the FDA if.

(a) The facility contravenes GSDP requirements.

(b) Any of the conditions under which the license was issued no longer exist.

(c) The information on which the approval was given is later found to be false.

(d) The circumstances under which the approval was given no longer exist.

6.2.2 Other penalties as provided for in section 129 of the Public Health Act, 2012, Act 851, related to contraventions to the provisions of this guideline may be imposed.

6.2.3 Other penalties as provided for in section 129 of the Public Health Act, 2012, Act 851, related to contraventions to the provisions of this guideline may be imposed.

7.0 ADDITIONAL NOTE

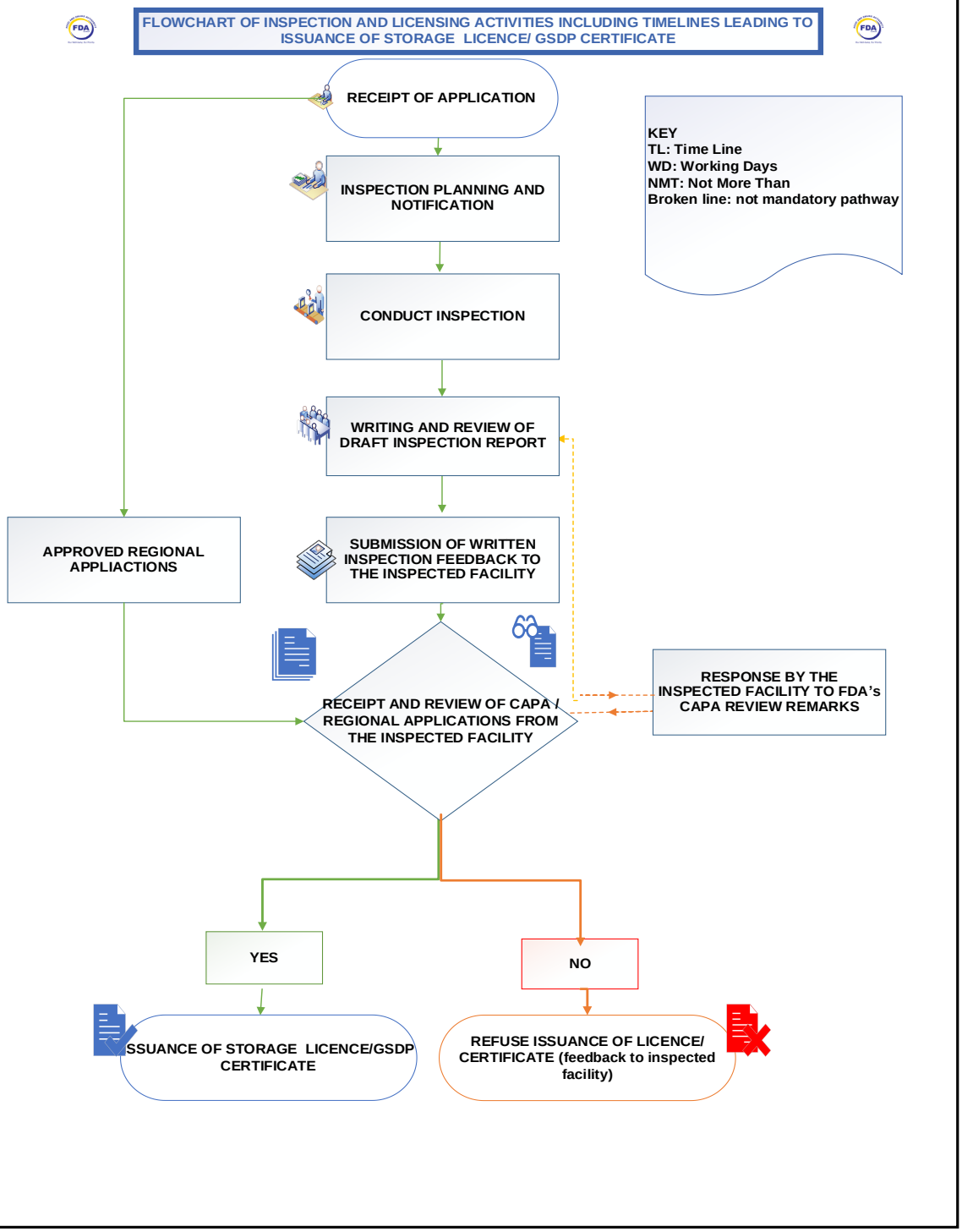
The storage facility where medical products and subsequently marketed in Ghana shall be subjected to Good Storage and Distribution Practice (GSDP) inspection in accordance with the requirements of current WHO. Applicants should refer to the Guideline on Inspection of Medical Products Storage Facilities (FDA/SFD/GDL - 01)

ANNEX 1: REQUIRMENTS FOR APPLICATION FOR VARIATION TO A MEDICAL PRODUCTS SUBSTANCES STORAGE FACILITYS

MAJOR VARIATION		
DESCRIPTION OF VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of ownership	If there is change of ownership of the Storage facility licensed	1. Application letter 2. Proof of business name registration reflecting the name of new owner 3. Deed of sale or transfer of 4. Proof of payment
Transfer of location	If the location of the facility has been physically transferred with changes in previously approved address	1. Application letter 2. Proof of business name registration reflecting the new address 3. New location address 4. Proof of payment
Additional Activity	**If there is an addition of a new storage category (Ambient or Cold Storage) to a previously approved location/address**	**1. Application letter** **2. Proof of business name registration reflecting the new address** **3. Application Forms** **4. Proof of payment**
MINOR VARIATIONS		
VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of activity	Change in the initial license activity	1. Application letter 2. Contract agreement to proof activity. 3. Proof of payment
Expansion of establishments	Expansion adjacent to existing licensed facility. Includes additional floors as well.	1. Application letter 2. Proof of payment
Change of business name	Change of business name without change in location of business owner	1. Application letter 2. Proof of business name registration reflecting the new name of the drug establishment 3. Proof of payment
Zonal change in address	Refers to change in the name/number of the street/building without physical transfer of the facility	1. Application letter 2. Document issued by the local authority as proof of zonal change. 3. Proof of payment
MINOR VARIATIONS- NOTIFICATIONS		

VARIATION	CONDITION	DOCUMENTS REQUIRED
Deletion of activity	Deletion of any approved/added distributor activity	1. Application letter 2. Termination of contract or conformance letter 3. Proof of payment
Transfer/addition of warehouse	Refers to the physical transfer of warehouse. Also refers to the addition of warehouse the existing or previously inspected warehouse.	1. Application letter 2. New location plan 3. Proof of payment

ANNEX 2: FLOW CHART



TIMELINES

LOCAL FACILITIES: NMT 3 months after receipt

NMT 5 WD

NMT 45 WD after the conduct of inspection

COMPANY: 25 WD to respond. (*may be varied*)
FDA: 20WD to review.
FOLLOW-UP INSPECTION REQUIRED: 20 WD after CAPA review.

NMT 10WD on approval

NMT 40 WD on issuance of licence/certificate.

ANNEX 3: CONTENTS OF A QUALITY MANUAL FOR A MEDICAL PRODUCTS SUBSTANCES STORAGE FACILITY

The quality manual is an official document created by the facility operator that lays out how its quality management structure works. It should include the quality policy and objectives and a highly detailed explanation of the quality control system being used. A quality manual includes the following:

(a) The scope of the quality management system, including details of and justification for any exclusion or non-application.
(b) The documented procedures for the quality management system, or reference to them.

(c) A description of the interaction between the processes of the quality management system.

The quality manual shall also outline the structure of the documentation used in the quality management system.

ANNEX 4: LIST OF DOCUMENTARY REQUIREMENTS FOR LICENSING OF A WHOLESALER OR DISTRIBUTOR OF PHARMACEUTICAL PRODUCTS, HERBAL MEDICINES AND FOOD SUPPLEMENTS.

Initial Application

1. Application letter addressed to the CEO
2. Filled Application form
3. Proof of Registered Business
4. Credentials of Authorized person (see section 1.3)
5. Site mater file
6. Location plan
7. Proof of payment

Renewal of application

1. Application letter addressed to the CEO
2. Filled Application form
3. Copy of initial certificate issued
4. Proof of payment

Reissuance of Lost Certificate or Destroyed Certificate

1. Letter of request
2. Affidavit of loss or destruction
3. Proof of payment

Voluntary cancellation of license

1. Letter of request
2. Original licence

ANNEX 5 - LIST OF REGIONAL OFFICES

OFFICE	ADDRESS	CONTACT
Head Office	No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie P.O, Box CT 2783 Accra. GPS: GA–237–7316	03022 35100
FDA Tema Heights	FDA Tema Heights, opposite Meridian Hotel, Tema	0551112225/0556759925/0264407571
Western Regional Office	Adjacent Fidelity Bank, Ghana Post Building, Takoradi Harbour P. O. Box MC 2129, Takoradi GPS: WS-406-1927	031 202 7558, 0544 338 829
Western North Regional Office	P. O. Box WS 51.Wiaso, W/R WH-0071-8745	0244470413/0207944200
Volta Regional Office	Agbasiape, Ho, close to St. Cecilia Roman Catholic Church GPS VH-0010-3089.	03620 26659, 0244399632, 0247 978 956
Upper West Regional Office	Controller Block, Ministries, P. O. Box 291 Wa. GPS: SW–022–9492	03920-20111, 0244 470 413
Upper East Regional Office	Regional Administration Building, P. O. Box 612, Bolgatanga GPS: UB-0034-4017	0247 717 744
Northern Regional Office	Regional Administration Building, P. O. Box TL 1763, Tamale GPS: NT–0066–3381	03672024935
North East Regional Office	North East Regional Coordinating Council (RCC)	0244721831

	Nalerigu-Ghana GPS:ME-8358-6858	
Eastern Regional Office	Hospital Road, Opposite Assemblies of God Church, P. O. Box KF 2431, Koforidua GPS: EN-011-2579	0277 705 752
Central Regional Office	UCC Credit Union Building Adjacent, CEDECOM Building, Pedu Junction P. O. Box CC 1373, Cape Coast GPS: CC-097-0402	033090110, 0245839521, 0504422905
Bono Regional Office	House No. 61A, Nkwabeng Extention, Sunyani. Near St. Mary's School. Opposite Goode Goode Spot. Postal address PMB, Sunyani GPS: BS-0054-2542	0352028791, 0265062697
Ashanti Regional Office	Regional Coordinating Council (RCC), next to Electoral Commission's Office P. O. Box ST 402, Kumasi GPS: AK-133-7324	0302-203-6027/70, 0507-187-420/1/2