FOOD AND DRUGS AUTHORITY

GUIDELINES FOR LICENSING STORAGE FACILITIES OF WHOLESALERS AND DISTRIBUTORS OF PHARMACEUTICAL PRODUCTS, HERBAL MEDICINES AND FOOD SUPPLEMENTS

Document Number : **FDA/DRID/DID/GL-WDL/2019/02**

Date of First Adoption : **15th March 2019**

Date of Issue : **26th July 2019**

Version Number : **02**

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LIST OF ABBREVIATIONS

GDP : Good Distribution Practices
SMF : Site Master File
CAPA : Corrective and Preventive Action
EPA : Environmental Protection Agency
FDA : Food and Drugs Authority
WDL : Whole sale Distributors License
GL : Guidelines
DID : Drug Inspectorate Department
Vmaj : Major Variation
Vmin : Minor Variation

1.0 INTRODUCTION

1.1 In pursuance to **Sections 122, 130, 131 and 132 of the Public Health Act, Act 851, 2012**, of the Republic of Ghana, these guidelines are hereby made to provide for the licensing of an entity's storage facility for the storage and distribution of pharmaceutical products and herbal medicines and food supplements.

1.2 Such entities may generally be considered as wholesalers or distributors of pharmaceutical products, herbal medicines or food supplements.

1.3 The wholesale or distribution shall be carried out under the supervision of a Pharmacist or a person approved by the Authority as having specialist knowledge in the article to be distributed (Refer to FDA "Guidelines for Selection of Authorized Person in the Pharmaceutical and Chemical Industry").

2.0 GLOSSARY

2.1 *In this guidelines, unless the context otherwise states;*

Applicant
Means the management of the wholesale or distributing entity or the Authorized person or a duly appointed person acting for and on behalf of the authorized person but with limited responsibilities to the technical sections reserved for the Authorized person.

Authority
Means Food and Drugs Authority

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

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 toll to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, substandard, and/or misbranded products.

Quality management system
Means a document with a collection of business processes focused on consistently meeting customer requirement and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction. It provides a proactive approach to identifying, evaluating and controlling potential risk to quality. It facilitates continual improvement process performance and maintenance of product quality.

Quality manual
A document stating the company management's intentions for operating the quality system. It includes policies for all areas of the storage, distribution, procedures and facility, affecting or that affect quality of product during distribution.

Standard operating procedures
An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; cleaning of premises and environmental control; sampling and inspection).

Site master file
Means a document prepared by the wholesale distributor containing specific and factual GDP information about the products and/or control of the storage conditions carried out at the site and during distribution process, closely integrated operations at adjacent and nearby building.

Variation
Refer to appendix 2

Notifications
means changes that could have minimal or no adverse effects on the overall safety, efficacy and quality of the FPP. Annual notification (AN) do not require prior acceptance, but must be notified to FDA within 12 months following implementation of the change.

Minor variation (Vmin)
means changes that may have minor effects on the overall safety, efficacy and quality of the FPP. Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the variation application.

Major variation (Vmaj)
means changes that could have major effects on the overall safety, efficacy and quality of the FPP. The documentation required for the changes included in this reporting type should be submitted. Prior acceptance by FDA is required before the changes can be implemented. A letter of approval will be issued for all major variations if and when the variation is considered acceptable.

Corrective action and preventive action (CAPA) Report
Means a report stating the defects and non-conformances issued by the FDA after a GDP inspection as well as steps taken to eliminate the causes of the non-conformances or other undesirable situations.

3.0 REQUIREMENTS

3.1 Documents

3.1.1 Application documents

3.1.1.1 An application for a wholesale or distributor license for pharmaceutical products, herbal medicines or food supplements shall be made in writing to the Chief Executive Officer of the Food and Drugs Authority Ghana.

3.1.1.2 The application shall be addressed to;

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2787
Cantonments-Accra

3.1.1.3 An application form shall also be completed in accordance with the sequence of appendices provided in the application form, and shall be dated, signed and stamped by the pharmacist and owner/authorized representative of the firm.

3.1.2 Documentary attachments

3.1.2.1 The application shall be submitted in duplicate together with:

- Copy of a valid business registration certificate,
- Proof of payment of the prescribed fee for wholesale licensing,
- A Site Master File (SMF) of the storage facility to be used for the distribution activity. This shall include a sketch of the location plan of the establishment indicating a clear direction with identified landmarks to locate the storage facility,
- Basic floor plan of the storage facility,
- Architectural engineering permit issued by the District, Municipal or Metropolitan Assembly where the facility is located (for stand-alone storage facilities).

3.1.2.2 All documents submitted shall be in English.

3.1.2.3 A copy of the submitted duplicate documents shall be endorsed by the FDA and returned to the applicant.

3.2 Evaluating Applications Submitted

3.2.1 Applications shall be reviewed by the FDA officers to ensure compliance with both administrative and technical requirements.

3.2.2 based on the outcome of the evaluation in 3.2.1 additional or supplementary documentation may be requested by the FDA.

3.3 GDP Inspection of the Facility

3.3.1 A successful evaluation of submitted documentation shall be followed by GDP inspection of the storage facility by the FDA Ghana.

3.3.2 The GDP inspection shall be conducted in line with the FDA's guideline for conducting GDP inspection.

3.3.3 Additional documentation shall be required during the GDP inspection of the facility as follows;

- Quality Management System,
- Quality Manual and standard operating procedures,
- Distributorship agreement with foreign source/supplier/manufacturer (i.e. between local importer and foreign manufacturer, local supplier and local wholesaler,
- Credentials of other qualified persons,

- Proof of ownership /lease agreement of the space/building y the establishment occupied,
- Relevant reference materials (GDP guide, standard practice guidelines),
- Other procedure, protocols, records, and reports as required by the relevant guideline with which the GDP inspection is being subjected to.
- List of products distributed by the entity.

3.3.4 Recommendations (if any) shall be issued by the inspection team to management of the facility immediately after completion of the GDP inspection.

3.3.5 The applicant shall submit a Corrective Action and Preventive Action (CAPA) report in respect of the recommendations issued. The CAPA shall indicate among others things timelines within which the applicant intends to complete each of the recommendations issued.

3.3.6 Upon successful implementation of the CAPA, a follow-up inspection may be conducted by the inspection team to ascertain the effectiveness of the implementation (where applicable).

3.3.7 A storage facility shall only be licensed after an expert review team has duly reviewed the inspection report and CAPA (where applicable) and found it to be satisfactory.

3.4 Post license inspection

3.4.1 All drug distributors and wholesalers licensed by the FDA shall be subjected to routine inspections following the applicable provisions for carrying out operations of such nature as stipulated in the Public Health Act, 2012, Act 851 of the Republic of Ghana. Applications for major variations may require post-licensing inspection prior to approval of the variation. Other violations to regulation may require a post-license inspection (i.e. investigations into safety, quality and efficacy of products distributed).

3.5 Conditions for renewal of license

3.5.1 An application for renewal of license shall be submitted to the FDA a month to expiry of the current licensed issued by the Authority.

3.5.2 The application shall capture details of any variation (as stated in appendix 2) applied for within the period. Documents that have already been submitted and have not under gone any changes need not be submitted for the second time.

3.5.3 The approved fee shall be paid in respect of an application for renewal of a wholesale or distributor license. (see approved fee schedule via https://fdaghana.gov.gh/images/Quick%20links/FDA%20FEES%20SCHEDULE.pdf)

3.6 Acceptable Variations

3.6.1 The following classes of variations are allowable under a licensed distributor or wholesaler. Note that the listed variations may not be exhausted enough to cover all possible variations as such clients are advised to contact the FDA for any guidance in this respect.

a. Major Variation
   i. Change of ownership,
   ii. Transfer of storage location,
   iii. Additional product list requiring different storage condition from the known list submitted during the GDP inspection.

b. Minor Variation-require prior approval
   i. expansion of establishment,
   ii. change of activity,
   iii. change of business name,
   iv. zonal change in address.

c. Minor Variation-Notification
   i. change of pharmacist or other qualified person,
   ii. deletion of activity,
   iii. transfer/ addition of storage facility.

3.6.2 The license holder shall inform the FDA Ghana of any changes listed above.

3.6.3 Information on any variation submitted to the FDA Ghana shall be accompanied by the requisite documentations as indicated in appendix 2 of this guideline.

3.6.4 Distributors or wholesalers intending to carry out minor variations can continue to do business provided such variations have been filed with the FDA Ghana not more than twelve months after implementation.

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3.7 How Variation Applications Are Handled

3.7.1 A variation application (including the filled variation application form-GMP/GSP-GDP) shall be submitted along with a declaration letter undersigned by the Head of Regulatory Affairs that declares there is no other change except for the proposed variation.

3.7.2 NOTIFICATIONS (“Do and Tell”)

I. If the notifications fulfill the requirements (conditions and supporting documents as per guidelines DID shall acknowledge receipt of a valid notification.

II. The DID shall respond to a notification within a period of 20 working days after receipt of the application.

3.7.3 MINOR VARIATION (PROIR APPROVAL)

I. If the application fulfills the requirements (conditions and supporting documents as per appendix 2) of a minor variation, DID shall issue approval in the form a written letter for the proposed change.

II. The DID shall issue the approval to the minor variation within a period of 30 working days after receipt of the application.

III. Management of the licensed facility shall implement/commence implementation of the variation within the next 30 days after receipt of approval from the FDA. This 30 days' allowable period for commencement of implementation shall be indicated in the letter of approval.

3.7.4 MAJOR VARIATION

I. If the application fulfills the requirements (conditions and supporting documents as per appendix 2 of a major variation, DID shall issue approval in the form a written letter for the proposed change.

II. The DID shall issue the approval to the major variation within a period of 60 working days after receipt of the application. This timeline may be reviewed downwards to 40 working days based on the urgency of the variation, for example if it borders on safety. The timeline may also be adjusted upwards on the basis of scientifically justifiable evidence.

III. Management of the licensed facility shall implement/commence implementation of the variation within the next 30 days after receipt of approval from the FDA. The allowable period of implementation shall be indicated in the letter of approval.

IV. The FDA reserves the right to re-categorize the application type, where it's deemed appropriate.

V. Where a re-categorization of the variation is done by the FDA, it shall be communicated to the facility only where additional conditions and documentations are required as per appendix 2. This shall be done within 15 working days after receipt of the application.

3.8 Sanctions: Revocation/Cancellation of license

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

3.8.1 The facility contravenes GDP requirements

3.8.2 Any of the conditions under which the license was issued no longer exist

3.8.3 The information on which the approval was given is later found to be false

3.8.4 The circumstances under which the approval was given no longer exist

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

3.8.6 The Authority shall take steps including closure to ensure that the Wholesale or distribution activity is stopped until otherwise decided by the Authority.

3.8.7 Measures towards enforcing section **3.7** may include the publication of the FDA's action on its website and other relevant media

3.9 Penalties

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

3.9.2 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.

3.10 Timelines

Refer to appendix 3

APPENDIX 1

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

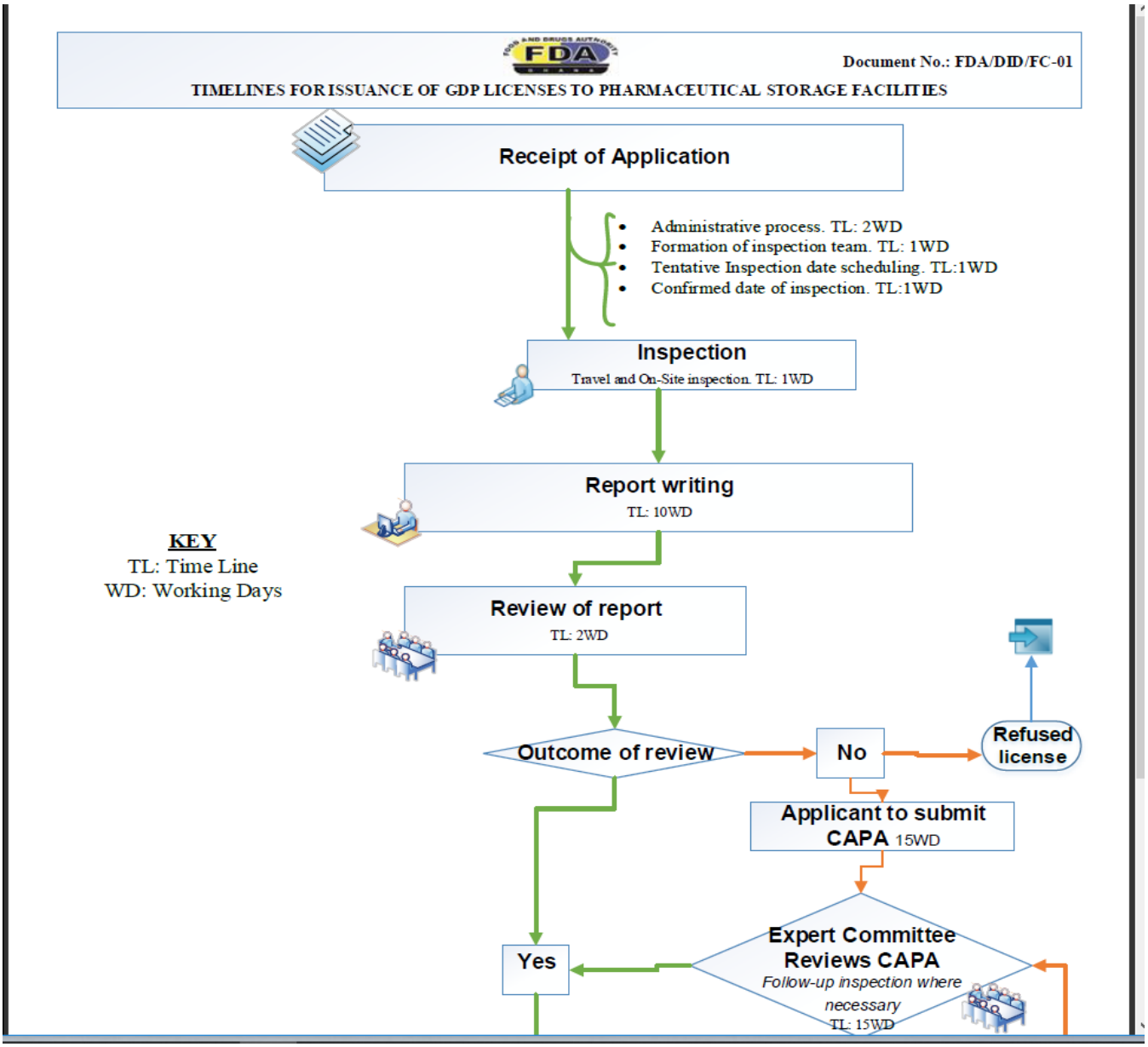
APPENDIX 2

LIST OF REQUIRMENTS FOR APPLICATION FOR VARIATION TO WHOLESALE OR DISTRIBUTOR LICENCE

MAJOR VARIATION		
VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of ownership	If there is change of ownership of the pharmaceutical manufacturing facility licensed	1. Application letter 2. Proof of business name registration reflecting the name of new owner 3. Deed of sale or transfer of the facility 4. Proof of payment for license
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
MINOR VARIATIONS		
VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of activity	If the entity engages in additional activities such as distribution, import or export. It also refers to a 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

APPENDIX 3: Timelines for licensing activities



APPENDIX 4:
Change History

SN.	Date	Ver No.	Description of Change (section)
1.	15/03/2019	01	Initial Issue
2.	26/07/2019	02	Inclusion of sections 3.7, 3.8, & 3.10