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|  |  **FOOD AND DRUGS AUTHORITY**   | **DOC. TYPE: FORM** |
| **DOC NO.: FDA/DRI/DED/AP-LMI** |
| **PAGE 1 OF 13** | **REV NO.: 00** |
| **EFFECTIVE DATE-05/2013** |
| **TITLE:**  **APPLICATION FORM FOR A LICENCE TO MANUFACTURE DRUGS, COSMETICS, HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES**  |

 CHECKLIST

 Applicant’s FDA Checklist Checklist

Covering Letter

Signed Declaration

Fully Completed Application

Site Master File

Environmental Protection Agency (EPA) Permit

 Name and Address of Suppliers of Equipment

List of Equipment and their Capacity

 Technical Management Agreement with any Organisation

Building Plans

**APPLICATION FORM FOR A LICENCE TO MANUFACTURE DRUGS,**

**COSMETICS, HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES**

This form shall be completed in duplicate by, or for, each manufacturer, accompanied by the prescribed application fee to:

# The Chief Executive

# Food and Drugs Authority

# P. O. Box CT 2783

# Cantonments, Accra

**Note:** The license application form must be accompanied by an application letter, a site master file and an Environmental Protection Agency permit.

For extra information refer to guidelines for licensing manufacturing industries. **FDA/DRI/DED/GL-LMI /2013/05**

# 1. Details of Manufacturer

1. Name of Business …………………………………………………………………………………
2. Postal Address……………………………………………………….………………………….

………………………………………………………………….…………………………………..

Tel ……………………………………...…Fax………………………………....…

E-mail………………………………………………………………………………

# 2. Location of proposed licensed premises

1. Street
2. Address: ……………………………………………………………………………………….

………………..………………………….………………………………………………………

…………………………………………………………………………………………………………

1. Postal Address (if different from business address above) …………………………

Tel: ……………………………………Fax………………………….

Email………………………………………………………………………………

1. Additional manufacturing sites if any\*

…………………………………………………………………………………………………………

…………………………………………………………………………………………………………

\* *Manufacturing is defined as production of products or engaging in any part of the process of producing the product or bringing the products to their final stage. This includes processing, assembling, packaging, labeling, storage, sterilizing, testing or release for supply of the products or of any component or ingredient*

**3.**

# Certificates

Provide a certified true copy of Certificate of Incorporation and Certificate of Commencement of Business from Registrar General’s Department.

A separate application is required in respect of each premises except where a group of buildings on one or more sites are engaged in making the same kind of product under the same direct production and quality control management.

# 4. Details of Manufacture

1. Product sub-category *(tick one or more boxes)*

|  |
| --- |
|  |

 Active pharmaceutical ingredient

Non-sterile drug

Sterile drug

Herbal product

Homeopathic product

Sterile device

Non-sterile device

Cosmetic product

Household chemical substance

1. Describe the range of dosage forms/types of devices to be manufactured

 *(tick the appropriate box(es))*

Tablets Aerosol-dispensed Medication

Capsules Powders (including oral and tropical)

Non-sterile ointments, Medical gas (including cream, jellies, pastes)

Liquid (including solutions, Chemical synthesis

Suspensions, elixir, tinctures)

Sterile non-injectables Plant/ animal extract

Suppositories Liquid for Oral use

Large volume parenterals Liquid for topical use

Small volume parenterals Not classified elsewhere

1. Indicate whether manufacture (for human, animal or any other purpose) include the

following *(tick as appropriate)*

Penicillin Large volume parenterals

Biological products Small volume parenterals

Cytotoxic drugs Hormones or Steroids

1. State other products to be manufactured at the same premises which do not fall within

the categories listed in (b).

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# 5. Contract Manufacture

1. Product stages of manufacture, excluding testing, which are to be contracted to another manufacturer.

|  |  |  |
| --- | --- | --- |
| **Product/ Stage**   | **Manufacturer**   | **Address**   |
|      |   |   |

1. Testing contracted to the manufacturer

|  |  |  |
| --- | --- | --- |
| **Nature of Test**   | **Name of Testing Laboratory/Service**   | **Address**   |
|          |   |   |

1. Products stages of manufacture, including testing, which are to be made or performed for another manufacturer.

|  |  |  |
| --- | --- | --- |
| **Product**   | **Manufacturer**   | **Address**   |
|        |   |   |

# 6. Key Personnel

 6.1 Person in charge of production

 Full Name…………………………………………………………………………………….

 Position in the company…………………………………………………………………….

1. Relevant qualification

|  |  |  |
| --- | --- | --- |
| **Name of Institution**   | **Duration of Study**   | **Certificates Awarded**   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |

1. Relevant Experience (*last job first*)

|  |  |  |
| --- | --- | --- |
| **Name of Company**   | **Duration**   | **Position Held**   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |

 6.2 Person(s) in charge of Quality/ Assurance.

 Full Name…………………………………………………………………………………….

 Position in the company…………………………………………………………………….

1. Relevant qualification

|  |  |  |
| --- | --- | --- |
| **Name of Institution**   | **Duration of Study**   | **Certificates Awarded**   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |

1. Relevant Experience (*last job first*)

|  |  |  |
| --- | --- | --- |
| **Name of Company**   | **Duration**   | **Position Held**   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |

# 7. Specification of the Plant

1. Equipment

Type Number of Units Specified Production Capacity

………………………… ……………………. ………………………………………….

………………………… ……………………. ………………………………………….

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………………………… ……………………. …………………………………………. ………………………… ……………………. ………………………………………….

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*(Attach supplementary list where necessary)*

1. What is the projected maximum annual capacity of the proposed plant?

…………………………………………………………………………………………………

…………………………………………………………………………………………………

Indicate number of shifts……………………………………………………………………

1. What are your anticipated sources of raw materials?

…………………………………………………………………………………………………

…………………………………………………………………………………………………

………………………………………………………………………………………………….

# 8. Water Supply, Treatment and Waste Disposal

1. What is your source of water supply?

………………………………………………………………………………………………….

1. Proposed water treatment method

………………………………………………………………………………………………….

1. Proposed effluent treatment methods before discharge

…………………………………………………………………………………………………

…………………………………………………………………………………………………

…………………………………………………………………………………………………

# 9. Number and Category of Employees

1. Estimated number of employees required

|  |  |  |
| --- | --- | --- |
| **Category**   | **Initial Capacity**   | **Full Capacity**   |
| Managerial  |   |   |

|  |  |  |
| --- | --- | --- |
| Senior Skilled  |   |   |
| Junior Skilled  |   |   |
| Unskilled  |   |   |

Would any expatriate be employed?..................................................................

1. If Yes, how many? And what are their Nationalities?

…………………………………………………………………………………………………

…………………………………………………………………………………………………

# 10. Enclosures

The following are to be submitted:

1. Name and address of suppliers of equipment.
2. Technical management agreement signed with any organization
3. Building plans.

# 11. State proposed date of commencement of business

 …………………………………………………………………………………………….

**12. Any additional information which applicant wishes to provide.**

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We hereby confirm that the answers given on this application form are true and correct to the best of our knowledge.

Name of Owner/ Director…………………………………………………………………………….

Signature…………………………………………………..

Date………………………………………………………..

Stamp…………………………………………………….

Name of Qualified Person…………………………………………………………………………

Qualification…………………………………………….

Signature……………………………………………….

Date…………………………………………………….

Stamp………………………………………………….

\*Witnessed by

Name …………………………………………………………………………….

Signature…………………………………………………..

Date………………………………………………………..

Stamp…………………………………………………….

(\* Senior Civil/ Public Servant, Minister of Religion)