APPLICATION FORM FOR A LICENCE TO MANUFACTURE DRUGS, COSMETICS, HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES

CHECKLIST

Applicant's check list		FDB double check
☐	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	☐

FORM FOR APPLICATION 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 Board
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.

1. Details of Manufacturer

a) Name of Business ……

b) Postal Address:……..…….

…….……

Tel ……..…Fax……...…

e-mail……

2. Location of proposed licensed premises

a) Street Address: …….

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b) Postal Address (if different from business address above)……

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Tel: ……Fax:……..

e-mail……

c) Additional manufacturing sites if any*

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** 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

a. 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 ☐

b. 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, (including creams, jellies, pastes)	☐	Medical gas	☐
Liquid (including solutions, suspensions, elixirs, tinctures)	☐	Chemical synthesis	☐
Sterile non-injectables	☐	Plant/animal extract	☐
Suppositories	☐	Liquid for oral use	☐
Large volume parenterals	☐	Liquid for topical use	☐
Small volume parenterals	☐		
Not classified elsewhere	☐		

b) Indicate whether manufacture (for human, animal or any other purpose) includes the following (*tick as appropriate)*

Penicillin	☐	Large volume parenterals	☐
Biological products	☐	Small volume parenterals	☐
Cytotoxic drugs	☐		
Hormones or steroids	☐		

c) 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

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

Products/stage	Manufacturer	Address

b. Testing contracted to another manufacturer.

Nature of Tests	Name of Testing Laboratory/Service	Address

c. 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 company……..

a Relevant qualifications

NAME OF INSTITUTION	DURATION OF STUDY	CERTIFICATES AWARDED

b. Relevant experience (last job first)

NAME OF COMPANY	DURATION	POSITION HELD

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

Full name ……...

Position in company……..

a. Relevant Qualification

NAME OF INSTITUTION	DURATION OF STUDY	CERTIFICATES AWARDED

b. Relevant experience (last job first)

NAME OF COMPANY	DURATION	POSITION HELD

7. Specification of the plant

a. EQUIPMENT

Type	Number of units	Specified Production Capacity
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……

(Attach supplementary list where necessary)

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

……..……..

……..……..…….....

Indicate number of shifts……

c. What are your anticipated sources of raw materials?

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……..……..

……..……..

8. Water Supply, Treatment and Waste Disposal

a. What is your source of water supply

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b. Proposed water, treatment method

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c. Proposed effluent treatment methods before discharge

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…….

9. Number and Category of Employees

a) Estimated number of employees required

Category	Initial Capacity	Full capacity
Managerial		
Senior Skilled		
Junior Skilled		
Unskilled		

b) Would any expatriates be employed? ……

c) If yes, how many? And what are their nationalities

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d) ……..……..……..

10. Enclosures

The following are to be submitted:

a) Name and address of suppliers of equipment.

b) Technical management agreement signed with any organization

c) Building plans.

11. State proposed date of commencement of business

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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*)