APPLICATION TO REGISTER AS AN IMPORTER OF BIOLOGICAL PRODUCTS

(***Tick the appropriate boxes to verify that required documentation is attached***)

CHECKLIST

Applicants (check)		**FDA staff (double check)**
□	Covering letter	□
□	Signed declaration	□
□	Current pharmacy council license	□
□	Registrar-general's certificate of registration	□
□	Evidence of claims	□

A. CONTACT DETAILS OF APPLICANTS (*MUST BE COMPLETED*)

1. Full name of applicant(s) (can be s company):

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……

2. Name of contact person(s) and Designation

……

……

3. Residential address of applicant(s):

……

……

4. Postal address of applicant(s):

……

……

E-mail: **Fax number:**

Telephone number(s):

5. Date of incorporation of company: (***please note that ONLY a body incorporated in Ghana can be appointed as a local agent for this application***)

_____/_____/_____

6. Company registration number:

……

……

7. Name of superintendent/resident pharmacist:

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8. Contact details of superintendent/resident pharmacist:

E-mail: **Telephone number:**

9. Registration number of superintendent/resident pharmacist:

I/We, declare that the information provided with this application is complete and correct.

Signature of contact person: Date:____/____/_____

Signature of superintendent pharmacist: Date:____/____/_____

(*if different from contact person*)

False declaration may lead to prosecution

NOTE: Please attach a copy each of the following documents:

I. Certificate of registration from the Registrar- General's department.

II. Current Pharmacy Council License (if a registered pharmacy).

B. BIOLOGICAL PRODUCTS TO BE IMPORTED (*Tick appropriately*)

1. Vaccines □
2. Biotechnology-derived therapeutic products □
3. Biological substance □
4. Biosimilar products □
5. Plasma derived medicinal product (BLOOD PRODUCTS) □
6. Cell-lines, tissues and live culture □

C. AVAILABLE COLD-STORAGE LOGISTICS AT YOUR DISPOSAL TO MANAGE COLD-CHAIN (*Tick appropriately*)

1. Cold room (+2ºC to +8 ºC) □
2. Freezer room (0ºC to -20 ºC) □
3. Refrigerator □
4. Combined refrigerator - water-pack refrigerator □
5. Combined refrigerator - ice-pack refrigerator □
6. Freezer (0ºC to -20 ºC) □
7. Cold/Cooler boxes (***product not appropriate for handling or transporting refrigerated products for longer than 3 to 4 hours***) □
8. Water packs, ice-packs, cool-packs and warm packs □
9. Temperature recording/monitoring device □
10. Digital temperature recorder □
11. Alarm system with visual and audible □
12. Temperature probes □
13. Chart recorder (***temperature recording between -20ºC to +15ºC***) □
14. Wall-mounted pen recording thermometer □
15. User programmable temperature data loggers □
16. Electronic shipping indicators □

17. Refrigerated van (+2ºC to +8 ºC) □
18. Freezer van (+2ºC to +8 ºC) □
19. Liquid nitrogen tank for liquid nitrogen storage □

NOTE: Please provide evidence of claim.

I/We, declare that the information provided with this application is complete and correct.

Name of contact person:……..

Signature of contact person: Date: _____/_____/_____

Name of superintendent/resident pharmacist:……..

Signature of superintendent/resident pharmacist: Date: _____/_____/_____
(*if different from contact person*)

Official stamp:

False declaration may lead to prosecution

Guidelines for importation of biological products

1. SCOPE

In pursuance of section…….. these Guidelines are hereby made to provide guidance to prospective importers on the procedure for importing products into Ghana. Importers are required to familiarize themselves with this document and the above law before initiating product importation.

2. DEFINITION OF TERMS

"Authority" means the food and drugs authority

"Product" means any article that is regulated under the Food and Drugs Law, which includes innovator biologicals, biosimlars, vaccines and blood and blood products and any articles that are used in the manufacture of these.

"Non-compliant product" means unregistered, counterfeit, substandard and any other product that shall be determined by the Authority.

"Reasonable quantities" shall be determined by the Authority

"Approved port" means Tema Harbor, Takoradi Harbor, Katoka international airport and other sea, air or land borders as may be approved by the Authority from time to time.

3. REQUIREMENTS

3.1 General requirements

a) Only corporate bodies duly registered by the Registrar- General's Department and licensed by the board shall be permitted to import a product.

b) All products imported shall have at least 60% of its shelf-life remaining on arrival at the port. This notwithstanding, products with a shelf-life of less than 24 months shall have at least 80% of its shelf-life remaining, on arrival at the port of entry.

c) Only registered products shall be permitted to be imported.

3.2 **Specific requirements**

a) **Drugs**

I. Only registered wholesale pharmaceutical companies, licensed by the pharmacy council may be permitted to import drugs

The following may also be permitted by the Authority to import reasonable quantities of drugs.

II. Retail pharmacies for retail in their shops only.

III. Medical doctors, dentists and veterinary surgeons for use in their clinics.

IV. Governmental, quasi-governmental agencies and non-governmental organizations (NGO's) that run health programmes and facilities

V. Patients with prescription for specialist drugs for their personal use

VI. Manufacturers' representative importing samples as per the Authority's sample schedule for registration purposes.

b) Clinical Trial Batches

Clinical Research Organisations may import products for the purposes of clinical trials per the procedure detailed below:

- Permit to import clinical trial batches shall only be granted to duly recognized clinical research organizations (CROs) that have protocols approved by the Authority to conduct clinical trial and been issued with a Clinical Trial Certificate in accordance with Section 23 of the Food and Drugs Law.
- Application to import samples for clinical trials shall be made to the Authority in writing accompanied by a completed import permit application form
- All import permits shall bear the full name and address of the innovator, the sponsor and the clinical research organization, the name/description of the investigational medical product, placebo and total quantity.
- Permit to import clinical trial batches shall be signed and dated by the principal investigator.
- Both the investigational medicinal product and the placebo shall be labeled to indicate they are samples for the conduct of clinical trials only.
- Permit to import investigational medicinal product and placebo shall be accompanied by the certificates of analysis.
- Products imported shall be inspected by officers of the Authority at the port of entry before they are released to the CRO.
- The Authority may order the re-exportation of the products intended for clinical trials if the Authority has any reason to believe that there is a protocol violation or any of provisions in these guidelines have been violated.

4. PRODUCT IMPORT PERMIT

4.1 Except otherwise provided by these Guidelines, import permits shall be granted before the importation of a product.

4.2 When applying for a permit, the following documents shall be submitted:

(a) Three (3) copies of the supplier's invoice.

(b)Three (3) copies of appropriately filled permit application forms.

4.3 Permits issued for importation of products shall be presented to Customs, Excise & Preventive Service (CEPS) ONLY ONCE, and shall not be re-presented for a second time in case goods are short landed.

4.4 At the point of clearance, the yellow copies (clients' copy) of the permit should be handed over to the FDA port official, and the white copy (original) taken to clear goods with customs.

4.5 Where goods are short-landed, a new import permit shall be obtained from the Authority.

4.6 Permits shall be valid for **ONE CALENDAR YEAR** from the date of issue.

4.7 A fee shall be charged for the processing of a permit submitted for importation. This shall be determined by the Authority from time to time.

4.8 Vetting of an application for importation and accompanying pro-forma invoices may take up to ten (10) working days

4.9 Applications which are found to fall short of any of the requirements in 4.4 above, shall not be approved.

5. **COMPLETION OF IMPORT PERMIT APPLICATION FORM**

5.1. All import permits shall bear the following:

a) Full name, postal address and premises address of both the importer and exporter

b) Name/description of product

c) Total quantity of product, in dosage units

d) Product registration number

e) Name of manufacturer and country of origin

f) Batch number

g) Total CIF value

h) Name of port of shipments and approved port of entry

i) Date, company stamp and signature

5.2. Additionally for drugs, the permit shall bear the following:

a) Full name, signature and registration number of the superintendent pharmacist.

b) Brand name and generic name of the product.

5.3. Products imported shall be inspected by officials of the Authority at the port of entry before they are released to the importer.

5.4. The above notwithstanding, any statute governing importation procedures and tax liabilities shall apply to an imported product.

5.5. An application for importation of a product may be rejected for several reasons. This may include, but not limited to:

a) A product not registered with the Authority.

b) A product with a potential for abuse

c) A product found to be fake, substandard and/ or adulterated.

d) A controlled drug when the national quota for that particular drug has been exhausted

5.6. All importers are required to renew their company license with the Authority annually.

6. SANCTIONS AND PENALTIES

6.1 Non-Compliant Products

The Authority may apply the following in case of the importation of a non-compliant product after detention and issuance of appropriate detention notice:

a) Order the re-export of the product at the cost of the importer.
b) Confiscate a non-compliant product, which may be destroyed and the cost of destruction borne by the importer, who may be prosecuted accordingly.

6.2 Bringing Into Compliance

a) The Authority may permit an importer to bring an imported non-compliant product into compliance with the law. Any sorting, processing, labeling/ re-labeling or analysis shall be supervised by an officer of the Authority at the expense of the importer.

b) Where the non-compliant product is unregistered, the importer shall be made to submit the product for registration and pay the appropriate fees in addition to a penalty to be determined by the Authority.

c) Importation of the drugs specified in Schedule 1 is prohibited.

d) Importation of the drugs specified in Schedule 2 is restricted. The Authority may, however, grant permit for the importation of these drugs, in of an emergency.

6.3 Restricted Drugs

a) The importation of the finished product specified in Schedule 2 is prohibited. Only their raw materials may be imported for local manufacture.

b) Products containing steroids are considered as drugs and shall not be permitted to be imported and used as cosmetics