

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR BLOOD AND BLOOD COMPONENTS LISTING**

**Document No. :** **FDA/SMC/BPD/AP-BPL/2015/07**

**Date of First Adoption :12th March, 2015**

**Effective Date :12th March,2015**

**Version No. :01**

**Application Form for Blood Products Listing**

*(To be submitted in duplicate, one comb-bound hard copy and one electronic copy. Please complete all relevant sections)*

**COVER LETTER ADDRESSED TO:**

**THE CHIEF EXECUTIVE**

**FOOD AND DRUGS AUTHORITY**

**P.O. BOX CT 2783**

**CANTONMENTS – ACCRA**

**GHANA**

**RETURN COMPLETED FORM TO:**

**CHIEF EXECUTIVE OFFICER**

**FOOD AND DRUGS AUTHORITY (FDA)**

**17 SOUTH LEGON COMMERCIAL**

**AREA, SHIASHIE**

**ACCRA**

*All information sought in this form shall be provided to enable the FDA process the application*

**SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER**

**Section 1 – Background Information**

**License number(s)**

If the blood facility making the application already holds or has previously held an existing license from the FDA please enter the license number(s) below

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of issuance:** |  | **License number:** |  |
| **Year of issuance:** |  | **License number:** |  |
| **Year of issuance:** |  | **License number:** |  |

**Other Licenses held**

If the blood facility making the application already holds a license issued by FDA and/or any other agency, please identify it by completing the grid below. To ensure clarity please enter ‘yes’ or ‘no’ against each license type in the appropriate column

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Collection |  |  |
| Testing |  |  |
| Processing |  |  |
| Packaging and Labelling |  |  |
| Release and Distribution |  |  |
| Further Manufacture |  |  |
| Other (if yes specify below) |  |  |
|  |  |  |

**Reasons for submission**

|  |  |
| --- | --- |
| Initial license |  |
| License renewal |  |

\*tick appropriately (✔)

**Section 2 – Applicant**

|  |  |
| --- | --- |
| **Applicant:** |  |
| **Legal name of blood facility:** |  |
| **Other names used: (***include trade name, doing-business-as, previous names, etc***.)** |  |
| **Trading as:** |  |
| **Mailing address of applicant: (***Include location of the post office***)** |  |
| **Physical Address: (***Include legal name, number, street, city, and district***)** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **Email:** |  |
| **Contact person’s information:**  **Legal name:**  **Email:**  **Telephone:** |  |
| **Contact person’s signature:** |  |

**Section 3- Products manufactured at the Site**

|  |
| --- |
| **Please specify by ticking in the box**  Whole blood  Red Blood Cells  Fresh Frozen Plasma  Platelets  Cryoprecipitate  Frozen RBC  Washed RBC  Leukocytes  Leukoreduced RBC  Recovered Plasma  Irradiated Blood  Fibrin Glue  Granulocytes   * Buffy coats * Serum Albumin * Coagulation factors * Immunoglobulins   Other (Please specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Section 4 – Declaration**

I/we apply for the license for a blood facility to the proposed holder named in this application form in respect of the activities to which the application refers.

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

**Signed**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_

**Print name (Block Capital**): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**State capacity in which signed**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_