FOOD AND DRUGS AUTHORITY

GUIDANCE DOCUMENT FOR BLOOD FACILITY LICENSURE APPLICATION FORM

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FOREWORD

The Ghana Public Health Act 2012, Act 851 requires that Blood, Blood components and Blood products manufactured in Ghana meet acceptable standards of Quality, Safety and Efficacy and at the same time be assessed to have been collected, tested, processed and stored in facilities that comply with current Good Manufacturing Practice, Good Storage Practice and Good Distribution Practice.

This document is intended to provide guidance to applicants for the completion of the License and Product Listing application forms in accordance with the Blood Facility Licensure and Product Listing requirements in Ghana.

The Food and Drugs Authority (FDA) license Blood Facilities involved in the collection, testing, process, store, release, and distribute Blood, Blood components and Blood products in Ghana and monitor their quality and safety profiles for Serious Adverse Blood Related Events (SABRE).

Submission of satisfactory administrative information on the Blood Facility will assist the FDA to assess the suitability of the Blood Facility for its intended use.

1.0 INTRODUCTION

All owners or operators of blood facilities that collect, test, manufacture, prepare, package and label, store under controlled conditions for further distribution, or process whole blood and blood components and products shall be required to license/register with the Food and Drugs Authority (FDA),pursuant to section 118 of the Public Health Act, 2012, Act 851. A list of all blood components and blood products manufactured, prepared, or processed for transfusion or commercial distribution shall be registered with the FDA. All blood products and/or blood components shall be registered and listed prior to the beginning of operation. Variation applications shall be submitted to update the licenses of blood facilities and the registrations of blood components and products not later than January of every year.

Blood facilities/industries located in Ghana that import and/or export or offer to import or export blood products or blood components shall be required to register with FDA. The name of the local agent, the name of each importer or exporter, and each contact person who import and/or export or offers for import or export of blood products and components shall be provided.

The applicant is required to complete the application forms, FDA/BPU/A-LBF/2015/01(APPLICATION FORM FOR LICENSING BLOOD FACILITIES IN GHANA) and FDA/BPU/A-LBBP/2015/01 (APPLICATION FORM FOR LISTING BLOOD AND BLOOD PRODUCTS IN GHANA) and submit to the FDA for approval. The process of approval of a blood facility application involves the review of supporting documents and inspections. The form (and accompanying instructions) shall either be purchased at the FDA's Head Office or downloaded from the FDA's website, www.fdaghana.gov.gh. The form shall be completed, signed and stamped and subsequently submitted to the FDA's Head Office, address provided in section 2 of the application form. Alternatively, the information may be submitted electronically / soft copy.

On variations, the blood facility shall not make any substantial change to the prescribed activities which it undertakes without the prior written approval of the FDA. Should a blood facility license holder need to change any detail contained in their licensure, they must submit an application to the FDA to vary the licensure. All applications must be submitted prior to the change being implemented by the license holder. Variations to the blood facility license may be classified as **administrative** – requiring a limited amount of assessment by an inspector or **technical** – requiring significant assessment by an inspector with possible scheduling of a site inspection.

On inspections, the blood facility shall be inspected by the FDA when you first apply and then at least once every year. After each inspection, the applicant shall be sent a follow-up letter describing the areas that needs attention to warrant or maintain authorization. For the blood facility to maintain its authorization, the facility shall be inspected at least once every year to ensure that it remains in compliance with the requirements of the FDA.

1.1 Scope

In pursuance of Section 118 of the Public Health Act 2012, Act 851, these Guidelines are hereby made to provide guidance to applicants on the procedure for licensing a Blood Facility in Ghana.

Applicants are encouraged to familiarize themselves with this document and the law before completing the registration form.

1.2 Definition of Terms

In these guidelines, unless the context otherwise states:

'Apheresis' the process by which blood drawn from a donor, after separating plasma or platelets or leucocytes, is re-transfused simultaneously into the said donor;

'Autologous Blood' the blood drawn from the patient for re-transfusion unto himself later on;

'Blood' and includes whole human blood, drawn from a donor and mixed with an anti-coagulant;

'Blood Bank Reagents' diagnostic substances manufactured for commercial distribution used to characterize and determine the acceptability of blood or products for transfusion purposes. These include Red Blood Cells reagents, blood grouping reagents, antibody to HBsAg, etc.

'Blood Component' a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor;

'Blood Facility' a place or organization or unit or institution or other arrangements made by such organization, unit or institution for carrying out all or any of the operations for collection, apheresis, storage, processing, packaging, labeling, and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components. We consider hospitals that freeze, deglycerolize, wash, irradiate, rejuvenate, or reduce the number of leukocytes from red blood cells to be a Blood Facility.

'Blood Product' a drug manufactured or obtained from pooled plasma or blood by fractionation, drawn from donors;

'Blood Products for Diagnostic Use' whole blood, red blood cells, or platelets shipped for further manufacture into non-injectable products.

'Broker/Warehouse' a broker, distributor, or warehouse that stores and redistributes source material for further manufacture, such as recovered plasma, source plasma, and whole blood, red blood cells, or platelets for diagnostic product use.

'Collection Facility' a facility that performs blood collections or apheresis, but does not test. If you also redistribute the final product after the parent blood bank has processed and returned products to you, then also check Distribution Center.

'Component Preparation Facility' an intermediate processing facility that prepares components from whole blood collected by a mobile or fixed collection site but does not perform product testing.

'Competent Technical Officer' someone with basic knowledge of the content of the application submission and able to respond appropriately to queries raised at the time of submission.

'Cryoprecipitated AHF' a preparation containing antihemophilic factor obtained from a single unit of plasma.

'Donor' a person who voluntarily donates blood after he has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor.

'Distribution Center' a facility that stores blood or blood products for transfusion or further manufacturing under specific controlled conditions prior to transporting it to the final user. We do not consider a transfusion service to be a "distribution center" since it holds the product over a relatively short period of time and does not intend to redistribute. If you are a transfusion service operating as a depot or distribution center for a blood bank, register as a Distribution Center and include the license number of the blood bank, if licensed.

'Fresh Frozen Plasma' single donor plasma prepared from whole blood within 8 hours of collection, or collected by automated apheresis, and stored at -18°C or colder.

'Hospital blood bank' a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

'Hospital Transfusion Service' a hospital that performs compatibility testing (cross matching) for blood or blood components but does NOT routinely collect allogeneic or autologous blood, or process whole blood into components (except Red Blood Cells and Recovered Plasma).

'Leukocytes/Granulocytes' white blood cells (leukocytes) collected from a single donor and suspended in a specific volume of original plasma intended for patient infusion.

'Leucapheresis' the process by which the blood drawn from a donor, after leucocyte concentrates have been separated, is re-transfused simultaneously into the said donor;

'Liquid Plasma' single donor plasma separated from red cells within 26 days after phlebotomy (35 days when CPDA-1 is used as the anticoagulant) and stored at 1-6°C.**'Other (specify)'**includes firms that manufacture fractionated blood derivatives, diagnostics, and other blood products, or independent facilities that irradiate blood products.

'Other' Other products not listed above that you manufacture for commercial distribution. This includes fractionated blood derivatives such as immune globulins, albumin, etc. Do not list these

products if you do not manufacture them. When submitting an initial product listing, list each product individually.

'Paid / Commercial / Professional Donor' a donor who gives blood in return for money or other form of payment

'Plasma' the fluid portion of one unit of human blood intended for transfusion which, in a closed system, has been collected, stabilized against clotting, and separated from red cells within 26 days after phlebotomy (35 days when CPDA-1 is used as the anticoagulant) and stored at -18°C or colder.

'Plasma Cryoprecipitate Reduced' plasma from which you have removed Cryoprecipitated AHF.

'Plasmapheresis' the process by which the blood drawn from a donor, after plasma has been separated, is re-transfused during the same sitting into the said donor.

'Plasmapheresis Center' a facility licensed by the FDAthat collects Source Plasma or Therapeutic Exchange Plasma for commercial distribution. If you also collect Whole Blood for a licensed for facility, tick, "Collection Facility" and include the license of the facility that receive the collected whole blood. Hospitals that perform plasmapheresis for research purposes only or to prepare transfusion products such as Plasma or Platelets, Pheresis, should NOT check this box.

'Platelets' platelets collected from a single donor and suspended in a specified volume of original plasma.

'Plateletpheresis' the process by which the blood drawn from a donor, after platelet concentrates have been separated, is re-transfused simultaneously into the said donor.

'Product Testing Laboratory' a separate facility that performs routine blood and plasma donor testing. You must also indicate whether you are independent or associated with a Blood Bank.

'Recovered Plasma' plasma derived from single units of whole blood, plasma, or as a by-product in the preparation of blood components from Whole Blood, for use in the manufacturing of licensed or unlicensed products.

'Red Blood Cells' red blood cells remaining after separating plasma from human blood, or collected by apheresis.

'RBC Deglycerolized' red blood cells washed free of the glycerol in which they have been stored.

'RBC Frozen' red blood cells stored at ultra-low temperature in the presence of a cryoprotective agent, and preserved for potentially long periods of time.

'RBC Rejuvenated' red blood cells treated with a rejuvenating solution, such as pyruvate inosine, to restore cell integrity.

'RBC Rejuvenated Frozen' red blood cells treated with a rejuvenating solution, then frozen and stored at ultra-low temperatures in the presence of a cryoprotective agent.

'RBC Rejuvenated Deglycerolized' redblood cells treated with a rejuvenating solution, frozen using a cryoprotective agent, and then washed free of the rejuvenating solution and glycerol.

'Replacement Donor' a donor who is a family friend or a relative of the patient –recipient.

'Responsible Person' a person who has been designated as the accountableofficer for specific products or processes within a blood facility. The same person may be named in this role at multiple sites of the same Area Blood Centre.

'Source Leukocytes' white blood cells intended as source material for further manufacturing use.

'Source Plasma' the fluid portion of human blood collected by plasmapheresis (except plasma derived by therapeutic plasma exchange) and intended as a source material for further manufacturing use. This includes source material intended for injectable and non-injectable products.

'Therapeutic Exchange Plasma (TEP)' plasma obtained from a patient who undergoes plasma exchange (also called therapeutic plasmapheresis). Do not list TEP that you immediately destroy. We consider TEP to be source material for further manufacturing use subject to licensure.

'Whole Blood' all blood collected from human donors for transfusion to human recipients using an approved anticoagulant preservative solution.

2.0 REQUIREMENTS FOR LICENSING OPERATIONS OF A BLOOD FACILITY/BLOOD BANKS/WHOLE BLOOD AND BLOOD COMPONENTS

These notes have been developed in order to assist you complete the application form. The form should be completed taking into account the operations to be conducted at the facility for which the authorization is intended.

The form is divided into nine sections, comprising -

Section 1	Background Information – to assist the FDA process the application
Section 2	Applicant Details
Section 3	Site Information
Section 4	Site Processes
Section 5	Site Personnel
Section 6	Responsible Person (Blood)
Section 7	Hospitals and blood banks supplied
Section 8	Further information
Section 9	Declaration

All sections of the form should be completed legibly in block capitals and typed**.**

Completed forms should be submitted in duplicate; one comb-bound hard copy and one electronic copy to-

Food and Drugs Authority
17 South Legon
Commercial Area
Shiashie – Accra

Submission should always be done by a competent technical officer.

Forms submitted without signatures will not be accepted. All personnel sections must be duly signed.

All sections except those marked with an asterisk (*) are mandatory; however, applicants are encouraged to complete the asterisked sections because doing so will assist the speedy processing of the application.

Section 1 - Background Information

- **License Number Box**

  If the company/organization making the application already holds or has previously held an existing license from the FDA, the number should be indicated in the licensure number box (see the example below).

Licence/Authorisation number(s)			
Year of issuance:	**xxxxx**	**Licensure number:**	**xxxxx**
Year of issuance:	**xxxxx**	**Licensure number:**	

The reason we ask for this information is that FDA uses a system of unique numbers to identify those companies, organizations etc. which it deals with. Providing any number(s) that we have previously allocated will assist FDA to ensure new applications are properly associated with previous applications made to the Authority (including those submitted to different divisions) and may assist FDA staff during data processing when queries arise. Where an applicant has more than one number this should also be included when completing the table.

If an applicant does not have an existing number leave this section blank and proceed to Section 2.

- **Other Licenses Held**

If an applicant already holds a license issued by FDA please identify it by completing the grid in this section. To ensure clarity please enter 'yes' or 'no' in the appropriate column (see example below):

	YES	NO
Collection	Yes	
Testing		No
Processing		No
Packaging and Labelling		No
Release and Distribution		No
Further manufacture		No
Other (if yes, specify below)		

Section 2 - Applicant Details

Blood Facility name

- Enter the name of the blood facility. This will be the name of the company (e.g. commercial organization) or organization (e.g. Area Blood Centre, Hospital) to which the licensure is to be issued.

Applicant (An Individual)

Enter the name of the individual who will be responsible for the blood facility authorization. The individual making the application (applicant) will be subsequently named as the Licensure Holder on the blood facility authorization where one is issued.

Trading As

- On occasions a company (more usually) or organization (rarely) operates under a trading name or trading style e.g. XYZ PLC trading as (t/a) ABC Enterprises. If a trading name is entered in this box on the application form it will subsequently be included on the Blood Facility Authorisation where one is issued.

Address (Mailing and Physical)

- Enter the details pertaining to the Blood Facility Name (above).

Telephone, Mobile, Fax, Email

- This information is for FDA business use and will aid FDA in administration and communications and assist in the speedy processing of the application.

If you are applying on behalf of the Proposed License/ Authorization Holder

- If the application form is completed by a third party on behalf of the applicant e.g. a regulatory consultant, please place a tick in the box.

Contact details for communications

- If no information is entered here all correspondence relating to the application for a Blood FacilityAuthorization, including queries, will be directed to the person named as the License Holder (above) at the address given for that person. Similarly, where an authorization is issued, it will be sent to the named License Holder. If the applicant wishes correspondence, queries and any issued authorization to go elsewhere i.e. to an administrative function, the relevant details should be entered in the boxes below "Contact Details for Communications".

Address for Invoicing Purposes

- If no information is entered here the invoice relating to FDA activities for the application for a Blood Facility Authorization will be directed to the person named as the License

Holder (above) at the address given for that person. If the applicant wishes the invoice to be sent elsewhere i.e. to a Finance Department, the relevant details should be entered in the boxes below “Address for Invoicing Purposes”.

Section 3 - Site Information

Section 3 – Site Information Please Note

The application form is divided into nine sections. The information provided in sections 1, 2 and 9 should only be sent once to FDA with each application form submitted. The information to be provided in the remaining parts of the application form (sections 3-8) is **site specific**. Consequently, if the application for the Blood Facility Authorization is to name more than one site (including contract sites) **one set of sections 3-8 will have to be submitted for each site to be named on the Authorization**. Please make additional copies of sections 3-8 as necessary to ensure you provide FDA with one set per site.

Definition: with respect to making an application for a Blood FacilityAuthorizationsite is as defined in the relevant legislation.

Site Number

- If known, enter the FDA site number. This is a unique identifier used by FDA and will assist in processing of the application.

Site Name

- If the site has a specific name unique from the address e.g. Something Building, enter the information in the site name box.

Site Contact Name

- Enter the name of the person to contact at the site (e.g. for inspection purposes). If no name is entered the contact name provided in section 2 of the application form or, if absent, the authorization holder name provided in section 2 of the application form will be used by FDA for site contact purposes.

Site Address (Physical and Mailing)

- Enter the details pertaining to the site.

Site Contact Details, Telephone, Mobile, Fax, Email

- This information is for FDA business use and will aid FDA in administration and communications and assist in the speedy processing of the application.

Site Usage

- Complete the grid to specify site usage. For clarity please enter ‘Yes’ or ‘No’ as appropriate in the relevant column.

Section 4 - Site Processes

Site Identifier Box

- At the top of the each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist FDA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

Proposed Processes to be Conducted at this Site

- Complete the grid to specify those processes intended to be undertaken at the site. For clarity please enter 'Yes' or 'No' as appropriate in the relevant column.

- Note the proposed processes grid extends to a second page. Both pages should be completed even if none of the processes on the second page are to be undertaken.

- Definitions for the processes are defined in the relevant legislation.

Section 5 - Site Personnel

- Enter in the grid the names of all personnel who will undertake the role of Responsible Person (Blood) **at this site**. Responsible person in relation to a blood facility means the person who has been designated as the responsible person for that blood facility. The same person may be named in this role at multiple sites but when this is so that person's name must be added to the separate sets of sections 3 – 8 submitted for each site.

- For each person named please provide the FDA with persons contact information.

- For each person named at section 5, a copy of section 6 of the application form (Responsible Person (Blood) – Details) must be submitted.

Section 6–Details of the Responsible Person (Blood)

Site Identifier Box

- At the top of the each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist FDA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

Nominee as a Responsible Person (Blood)

- Enter the title, name and business address and physical address of the person who is being nominated for the role of Responsible Person (Blood) at the site specified at section 3. Providing the telephone, mobile, and fax numbers and email address for the person will aid FDA in administration and communications and assist in the speedy processing of the application.

Status

- Tick whether the person being nominated for the role of Responsible Person (Blood) will be a permanent employee of the blood facility specified at section 2 of the application form or if the person being nominated will be a consultant offering contracted services to the Blood Facility.

Consultant

- If consultant was ticked in the status box (above) please answer the questions in the consultant box. When answering the question about frequency of visiting the site it is important that the information provided is sufficiently detailed and accurate for proper assessment by FDA.

Qualifications

- Only relevant qualifications need be provided. Include membership of relevant professional societies.

Experience

- Detail the experience that makes the person being nominated as Responsible Person (Blood) suitable to hold the position. Relevant experience obtained can be provided.

Signature

- Both the person being nominated for the role of Responsible Person (Blood) and the applicant named at section 2 of the form must sign section 6 of the application form. FDA reserves the right to independently contact the person named as the nominee for the role of Responsible Person (Blood) to verify the veracity of the application.

Reminder - one copy of section 6 of the application form (Responsible Person (Blood) – Details) must be submitted for each person named at section 5.

Section 7–Hospitals and blood banks supplied

Site Identifier Box

- At the top of the each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist FDA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

Details of Hospitals and Blood Establishments Supplied

- Provide the names and addresses of all the hospitals or blood establishments supplied with blood or blood components from the site specified at section 3. The list must include not only hospitals and/or blood establishments supplied in Ghana but also any hospitals and/or blood establishments outside Ghana that are supplied with blood or blood components. If the number of hospitals and/or blood establishments supplied is greater than the number of boxes available in section 7 of the application form please make additional copies of the page. If additional copies are made please write the total number of copies of section 7 (including the original) in the box at the bottom of the page. This may be entered in the box on all copies or just the original.

Section 8–Further Information

Site Identifier Box

- At the top of the each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist FDA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

Facilities on Site

- On a separate sheet of paper provide a brief description (approximately 500 words) of relevant facilities on the site specified at section 3 to support the application for being named on a Blood FacilitiesAuthorization e.g. the facilities available for collection, testing and storage of blood, facilities for processing blood and the processing undertaken, facilities for storage and distribution of blood and blood components. Please include at the top of the separate sheet the information held in the Site Identifier Box (as shown at the top of section 8) for the relevant site.

Additional Information

- Provide any further information that may assist in supporting and processing the application. If necessary use a separate sheet of paper; if a separate sheet is used please note this fact in the additional information box and include at the top of the sheet the information held in the Site Identifier Box (as shown at the top of section 8) for the relevant site.

Section 9–Declaration

Declaration

- The applicant named at section 2 of the application form must sign and date the application form and state in what capacity the form was signed.

When complete send the form to the address given in section 2 of the form. Please remember –

1. The applicant must sign the declaration.
2. For each person to be nominated as a Responsible Person (Blood) both the applicant and the person nominated must sign the relevant part of the form (section 7).
3. Information to support the nomination of Responsible Person (Blood) should be provided e.g. copies of relevant certificates (for qualifications or professional societies), copies of a relevant curriculum vitae etc.
4. At the time of inspection the sites to be inspected should be properly prepared for inspection with all required systems and documentation developed and suitable for purpose.
5. Information provided on the application form will be included on the Blood Facility Licensure where one is issued. If any of the information subsequently requires changing it is the responsibility of the Holder to **inform FDA in advance of any change** by submitting a variation to the License.