

REGISTRATION PATHWAY AND TIMELINES

BIOLOGICAL PRODUCTS UNIT
FOOD AND DRUGS AUTHORITY
(FDA)

SCOPE

In pursuance of Section 118 of the Public Health Act 2012, Act 851, the registration process flow is hereby made to provide guidance to applicants on the registration pathway and timelines for **PREQUALIFIED Biological Products** in Ghana

Application received at client service. Client service perform pre-evaluation assessment. If satisfied, application fee is paid. Fees paid (base on product category) . Documentation directed to the appropriate division by CEO.



Application acceptance phase

Acknowledgement letter sent to applicant

Evaluation phase



Evaluation of registration application documents at dossier evaluation meetings: Summaries, including Product Summary Files and representative registration samples are evaluated



Product Registration committee phase

Memo prepared to invite product registration committee members to a meeting



Committee members review evaluation report and make recommendation to the authority



Product Registration committee recommends rejection of application

Product Registration committee recommends approval of application

Product Registration committee recommends deferral of application

Decision phase

The CEO reviews recommendations of the product registration committee and a final decision is made on the application



Registration application **NOT APPROVED**. Applicant is notified of the decision within thirty days of the refusal. Applicant may appeal the decision under section 118 subsection (6) part (a) of the public health Act 2012

Registration application **APPROVED**. Applicant is notified of the decision. A registration number is generated and entered into the register under section 118 subsection (5) part (b) of the public health Act 2012

Registration application **DEFERRED** based on certain conditions. Conditions are communicated to the applicant. Further evaluation of additional documentation may be needed. When conditions are fulfilled, the registration application is subsequently approved

TIMELINES FOR REGISTRATION (WORKING DAYS)

