

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 **Non-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

Registration samples ,method of analysis and AMV sent to the FDAQCL

Evaluation of registration application documents commences- quality, safety and efficacy data critically evaluated against regulatory requirements. Following evaluation, applicant may be advice to submit additional documents.

Registration committee phase

Review of evaluation report by a peer reviewer

Memo prepared to invite product registration committee members to a registration meeting

GMP audit report

Committee members review evaluation reports and make recommendation to the CEO

Analytical report from FDAQCL

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 recommendation s 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 (3 years validity period)**. 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 **APPROVED COND- TIONALLY (1 year validity period)** based on certain conditions. Conditions are communicated to the applicant. Favourable post-registration safety /efficacy data may warrant extension of the initial one year by an additional two years. Applicant is notified of the extension

TIMELINES FOR REGISTRATION (WORKING DAYS)

