



FOOD AND DRUGS AUTHORITY (FDA)

MEDICINAL PRODUCT (FAST-TRACK) REGISTRATION PATHWAY AND TIMELINES

DRUG AND NUTRACEUTICALS REGISTRATION DEPARTMENT (DNC)

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

Classification, Application number assignment, and 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, a applicant may be advice to submit additional documents.

Review of evaluation report by a peer reviewer

REGISTRATION COMMITTEE PHASE

Convening of Product Registration Meeting

GMP audit report

Committee members review evaluation reports and take Decisions

Analytical report from FDA CLSR

DECISION PHASE

Product Registration committee decides **Approval** of application

Approval letter/Certificate of registration issued

Product Registration committee decides **Deferral** of application

Responses to query submitted to the FDA by applicant not later than 12-months from the date of first deferral, 6month on second deferral and 3months on third deferral

Formal acknowledgment forwarded to the applicant

Technical assessment & decision based on the recommendations of the previous product registration meeting

Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application) two weeks after product registration meeting 2

Product Registration committee decides **Rejection** of application

May appeal decision within 60 days. (Refer to the Guidelines for Registration of Allopathic drugs (FDA/DNC/GDL-01/03))

IF ACCEPTED

Please note :

- 1.The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client.
2. The counting of weeks in the chart therefore does not include time periods when applicant is expected to submit further documentation, clarification / justification to the FDA.
- 3.Time for handling appeal will not be counted as part of the regular processing time.
- 4.The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

TIMELINES FOR FAST-TRACK REGISTRATION

