



FOOD AND DRUGS AUTHORITY (FDA)

MEDICINAL PRODUCT VARIATION PROCESSING PATHWAY AND TIMELINES

DRUG AND NUTRACEUTICALS REGISTRATION DEPARTMENT (DNC)

Application received at client service. Documentation directed to the appropriate division by CEO.

APPLICATION ACCEPTANCE PHASE

Acknowledgement letter forwarded to applicant (where applicable). Note: Notification shall be completed within 4 weeks.

EVALUATION PHASE

Samples, method of analysis and AMV sent to the FDA CLSR (where applicable)

Evaluation of variation application commences. Following evaluation, applicant may be advice to submit additional documents.

Review of evaluation report by a peer reviewer

GMP audit report (where applicable)

Variation Decision Communicated to Applicant

Analytical report from FDA CLSR (where applicable)

DECISION PHASE

Approval of application

Approval letter issued

Deferral of application

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

Rejection of application

May appeal decision within 60 days.

IF ACCEPTED

Technical assessment & decision based on the previous product deferral comment.

Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application)

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 variation

