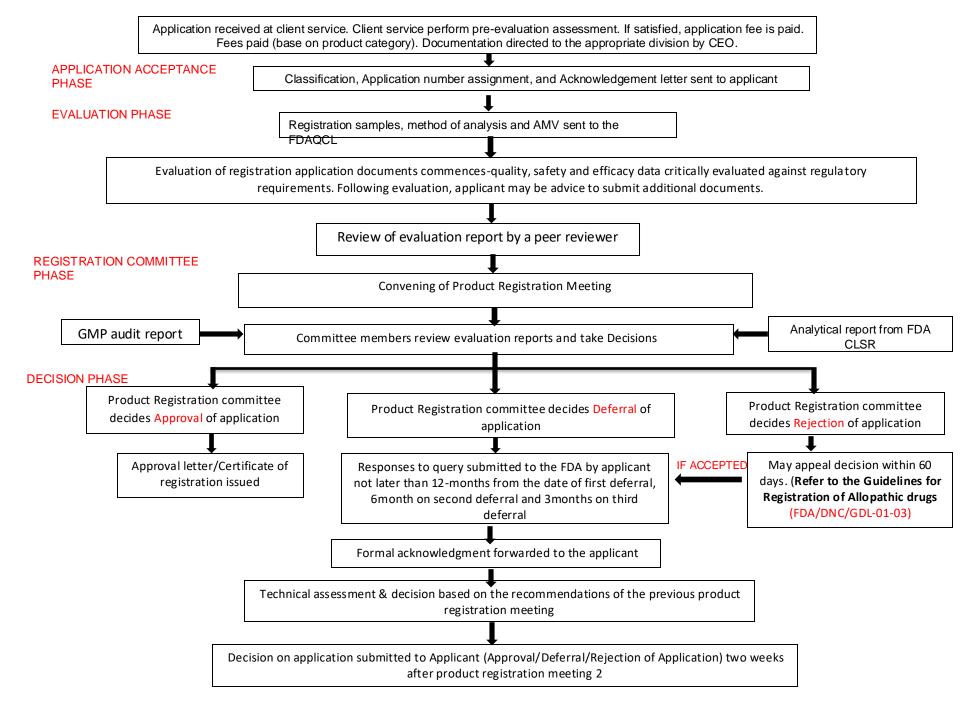


FOOD AND DRUGS AUTHORITY (FDA)

MEDICINAL PRODUCT REGISTRATION PATHWAY AND TIMELINES

DRUG AND NUTRACEUTICALS REGISTRATION DEPARTMENT (DNC)



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 REGISTRATION

Receipt of documentations at client service Clock Start Acknowledgement of registration application 4 Weeks after Submission Evaluation of registration application and End of Week 16 - (week 10 - 16) Laboratory analysis of registration samples End of week twenty (Week 16-20) Registration committee meeting End of week twenty-two (week 20 -22) Decision on application submitted to Applicant If application is deferred, or appealed decision to a rejected application is accepted Not later than 12-months from the date of first deferral, 6 months on second deferral and 3 months on third deferral. Responses to Query submitted to the FDA End of week 4 from submission of gueries (week 26 from initial Formal acknowledgement to the applicant submission) End of week 12 from submission of queries (week 34 from initial Technical assessment submission) End of week 16 from submission of queries (week 38 from initial Decision on application submitted to Applicant submission)