

MEDICINAL PRODUCT REGISTRATION TIME-LINES

RE-REGISTRATION

Please note

- 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
- Time for handling appeal will not be counted as part of the regular processing time.
- The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

E-REGISTRATION

DRI/DER/OTL-11/1.0

Submission of application from applicants

End of week four (week 4)

E-Acknowledgment (2weeks)

Formal acknowledgement letter forwarded to applicant 4weeks after submission

End of week sixteenth (week 10)

Application reviewed submitted to Product Registration Meeting

End of week twenty two (week 10-12)

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

Deferral

Approval letter /
Certificate of
registration issued

Responses to query submitted to the FDA by applicant not later than 3-months from the date

E-Acknowledgment

E-Alert on the decision

End of week four from the submission of queries (week 16 from initial submission)

Formal acknowledgment forwarded to the applicant

End of week twelve from sub of gueries (week 3 from initial submission)

Technical assessment & decision (approval / deferral) based the recommendations of the previous product registration meeting