Stability Studies Review and Evaluation Time Frame

Scope:

This guidance applies for any stability studies submitted for Review and Evaluation according to the pharmaceutical product country of origin.

Objective:

This guidance aims to provide applicants with the time frames required for Review and Evaluation of the stability studies for pharmaceutical products submitted according to the pharmaceutical product country of origin.

- **Process Time Frame:**

	Process of the Stability General Administration	Locally Manufactured Pharmaceutical Products	Imported Pharmaceutical Products from Reference Country	Imported Pharmaceutical Products from Non-Reference Country
1	Appointment Request	7 MWD	———	7 MWD
2	Tracing of the Stability studies	21 MWD	———	Acc. to Company (3)
3	Reviewing	5 MWD (1)	10 MWD (1)	10 MWD (1)
4	Technical Evaluation	30 MWD (2)	20 MWD (2)	20 MWD (2)
5	Issuing of Approval Technical Report	15 MWD	10 MWD	10 MWD
6	Issuing of Evaluation Comment Report or Subject Technical Report	10 MWD	5 MWD	5 MWD

(1) **For Pharmaceutical Products in which submitting CTD file is a must for their approval**: 5 MWD
(2) **For Pharmaceutical Products in which submitting CTD file is a must for their approval**: 10 MWD
(3) **Tracing Acc. To Company:** according to covering letter submitted by Applicant Company suggesting dates for holding on-line tracing visit.

Note:

- For stability studies of pharmaceutical products represented to the Stability General Administration according to fast-track requesting speeding up the process so that it's finished within 15 working days from the date of receiving of the fulfilled Fast Track request according to the announcement published on EDA Website.
- All Emergency Products will follow fast-track time frame in all Steps.

Abbreviations:

MWD: Maximum Working Days