

Jan. 31, 2018

CAPA Announces the start of FAST TRACK registration for MD

CAPA will start receiving TF's for registration of single use, sterilized MD with immediate effect on Fast Track with higher official fees as follow:

Action required	Est. Time needed by CAPA
Requesting Date for TF submission by email	CAPA answers in 2 days with a date at most
Fixed submission date for TF's	Within 5 working days at most
TF review and sending final reviewer's comments/requirements	Within 5 working days at most
Supervisor final review to present for Tech. committee	Within 5 working days at most

Official fees:

Registration fees/TF- Fast Track	20,000 Egyptian pounds
Re-registration fees/TF- Fast Track	7,500 Egyptian pounds

Variation department also accepts changes on registered products according to Fast Track as follows:

Action required	Est. Time needed by CAPA
Submission of TF's for review	Every day except Tuesdays
Number of TF's per each manufacturer	No limit for number of TF's
Review of required changes and deciding on CAPA requirements	Within 3 working days at most
Final revision to present TF's for Tech. committee	Within 3 working days at most

Official fees:

Changes required for a registered MD	5000 Egyptian pounds
Changing manufacturing address	15,000 Egyptian pounds
Requesting original registration license instead of a lost one	2500 Egyptian pounds

Applicants for registration or variation departments should submit mandatory vigilance requirements before granting the required licenses.