

TARGETTED TIMELINES FOR APPROVALS OF COMPLETE APPLICATIONS BY DCG (I) OFFICE

S.NO.	APPLICATION FOR	TIME IN WORKING DAYS
A.	EXPORT RELATED CLEARANCES	
1.	EXPORT NOC	10
2.	BE NOC FOR EXPORTS	28
B.	OTHER CLEARANCES	
3.	DUAL USE, RULE 37 & NEUTRAL CODE	20
4.	ADDITIONAL INDICATION ETC.(1 ST RESPONSE)	45
5.	FORM 10	30
6.	TEST LICENCE	30
7.	a) NEW DRUGS & CLINICAL TRIALS APPLICATIONS FOR OTHER THEN BIOLOGICALS (1 ST RESPONSE)	45
	b) NEW DRUGS (MARKETING AUTHORIZATION) APPLICATION FOR BIOLOGICALS (1 ST RESPONSE)	90
	c) CLINICAL TRIAL APPLICATION FOR BIOLOGICALS AS PER GUIDANCE DOCUMENT TO INDUSTRY (1 ST RESPONSE)	45
8.	FDC (1 ST RESPONSE)	45
9.	ENDORSEMENT OF ADDITIONAL PRODUCTS ON REGISTRATION FOR MEDICAL DEVICES	60
10.	ENDORSEMENT OF ADDITIONAL PRODUCTS ON REGISTRATION FOR OTHER THAN MEDICAL DEVICES	90
11.	REGISTRATION	120*
12.	REGISTRATION (1 ST RESPONSE)	45

***Subject to all clearances including testing by CDTL/CDL as applicable.**

Note:

- (i) It is expected that response to queries shall be given in complete and at earliest.
- (ii) Secondly, this office is contemplating to scrutinize the application with respect to completeness prior to acceptance (for time frame based disposal)

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