30-05-14

CDSCO

TIMELINES

S. No.	Type of application	Timeline in days
1.		
a)	New Drug including Biological, Medical Devices/Clinical Trials/Global Clinical Trials/New Claims in consultation with NDAC/MDAC	180
b)	IND Applications in consultation with IND Committee	180
c)	Subsequent New Drugs	120
d)	Clinical Trial Protocol Amendments (If Consultation of NDAC is not required)	60
2.	Fixed Dose Combination in consultation with NDAC	180
3.	Import Registration of Drugs and Medical Devices	270
4.	Endorsement of Additional Product in Registration Certificate	120
5.	Rule 37 & Neutral Code	60
6.	NOC for Form 29 (Biological and Medical Devices)	60*
7.	CLAA in Form 28/28-D/28-E/27-C etc.	60
8.	Import License in Form 10	45
9.	Test License in Form 11	45
10	Bioavailability /Bioequivalence (BA/BE) Study	45
11.	Extension of Shelf Life for export	45
12.	Export of Biological samples	45**
13.	Registration of Cosmetics	90
14.	Registration of Ethics Committee	100
15.	Post Approval Changes (major) in consultation with CDL, NDAC	180
16.	Post Approval Changes (minor)	90
17.	BA/BE site approval (after receipt of Joint Inspection report)	60
18.	Written Confirmation as per EU Directives	30

*If Inspection is involved, the time line is from the date of receipt of the inspection report.

**After obtaining BA/BE NOC

Note: In case of query or explanation, the time line will be from the date of receipt of the response.

30-05-14

(Dr. G.N. Singh)
Drugs Controller General (I)

To

1. JDC (I)/DDC(I)s/ADC(I)s, CDSCO HQ
2. All Zonal/Sub Zonal offices of CDSCO

Copy to: PPS to DGHS/PS to AS&DG/PS to JS (R), MoHFW