CDSCO

Dated 20.02.2020

Targeted internal timeline for processing and disposal of applications by CDSCO

A) Drugs, Biologicals & Cosmetics

S.No	Type of application	Targeted internal timeline in working days
1.	New Drugs/ Investigational New Drugs	
	a. IND Applications in consultation with Subject Expert Committee (SEC)	30
	b. New Drug including Biological, /Clinical Trials/Global Clinical Trials/New Claims in consultation with Subject Expert Committee (SEC)	90
	c. Subsequent New Drugs (SND) with Subject Expert Committee (SEC)	90
	d. Fixed Dose Combination in consultation with Subject Expert Committee (SEC)	90
2.	Import Registration of Drugs & Biologicals	270
3.	Import License in Drugs & Biological	45
4.	Import post approval changes for drugs :	
	a. Major	180
	b. Minor	90
5.	Endorsement of Additional Product in Registration certificate	120
6.	Rule 37 & Neutral Code	60
7.	Grant of permission for manufacturing of : a. New drug or investigational new drug for CT, BA or BE study or for examination, test and analysis (CT – 11) b. Formulation of unapproved API for test or analysis or CT or BA or BE study (CT-14) c. Unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or CT or BA or BE study (CT- 15)	7
8.	CLAA in Form 28/28-D128-E/27-C etc.	60
9.	Licence to import new drug or investigational new drug for the purpose of clinical trial or bioavailability or bioequivalence study or for examination, test and analysis (CT-17)	7
10.	Permission to conduct Bioavailability /Bioequivalence (BA/BE) Study for new drug or investigational new drug (CT-07)	90
11.	Extension of Shelf Life for export	45
12.	Registration of Cosmetics	90
13.	Registration of Ethics Committee (CT-02)	45
14.	Biological Post Approval Changes	
	a. Major in consultation with CDL, SEC	180
	b. Minor	90
15.	Permission for BA-BE study and its Post Approval Changes for export purpose	15
16.	Registration of BA/ BE study center (CT-09)	90
17.	Written Confirmation (WC) as per EU Directives	20
18.	Permission to Import small quantity of drugs for personal use	3

B) Medical Device & In-vitro Diagnostics:

S.No	Type of application	Timeline in working days
1.	Grant of Test License to manufacture for test, evaluation, clinical investigations, etc.(MD-13)	30
2.	Grant of Import License (MD-15)	270
3.	Grant of Test License for import for test, evaluation, clinical investigations, etc.(MD-17)	30
4.	Permission to Import small quantity of medical device for personal use.(MD-21)	7
5.	Permission to conduct Clinical Investigation (MD-23)	90
6.	Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device (MD-25)	90
7.	Permission to import or manufacture medical devices which does not have its predicate device(MD-27)	120
8.	Permission to import or manufacture new in vitro diagnostic medical devices(MD-29)	90
9.	Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer (MD-40)	45
10.	Licence/Loan License to Manufacture for Sale or for Distribution of Class A or Class B Medical Device (MD-5)/(MD-6):	
	a. For Class A Medical Devices:	
	i) Grant of license by SLA	45
	ii) Audit of the manufacturing site by the registered Notified Body from the date of issue of License by SLA	120
	b. For Class B Medical Devices:	
	i) Audit of the manufacturing site by the registered Notified Body from the date of application	90
	ii) Inspection Report submitted to SLA	30
	iii) Grant of license by SLA	20
11.	Licence/Loan License to Manufacture for Sale or for Distribution of Class C or Class D medical device(MD-9)/(MD-10):	
	a. Completion of scrutiny from the date of online submission of application	45
	b. Inspection of manufacturing premises from the date of application	60
	c. Grant of license from the date of receipt of Inspection report.	45
12.	Application for post approval change in manufacturing Licenses Prior approval to be obtained from CLA/SLA in major change	45
13.	Application for post approval change in Import Licenses Prior approval to be obtained from CLA/SLA in major change	60

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