Delivered on 13/02/2014 at the office of DCGI.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A-WING', DR. A.B. ROAD, WORLI, MUMBAI-400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : idma@vsnl.com
idma1@idmaindia.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE

1st February 2014

Dr G N Singh
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhavan; Kotla Road
New Delhi

Subject: Targeted timelines for approvals of complete application by DCG(I) office

Dear Sir,

We refer to the timelines released recently for approvals of various applications made to DCG (I) office. In this context we would like to request you to consider the following suggestions:

S No	TYPE OF APPLICATION	TIMELINE RELEASED (days)	TIMELINE REQUESTED (days)
1(a)	New Drug including Biological, Medical Devices / Clinical Trials / Global Clinical Trials / New Claims in consultation with NDAC / MDAC	180	90
1(b)	IND Applications in consultation with IND Committee	180	90
1(c)	Subsequent New Drugs	120	30
1(d)(i)	Clinical Trial Protocol Amendments (if consultation of NDAC not required)	60	15
1(d)(ii)	Clinical Trial Protocol Amendments (if consultation of NDAC is required)	-	30
2	Fixed Dose Combination in consultation with NDAC	180	90
3	Import Registration of Drugs and Medical Devices	270	30

AFFORDABLE MEDICINES FOR ALL

Registered under the Societies Reg. Act XXI of 1860 Reg. No. Bom. 111/1961 G.B.B.S.D.
Registered under the Bombay Public Trust Act, 1950 (Bom. XXIX of 1950) Reg. No. F-1514 (Bom.) Dt. 11-4-67

S No	TYPE OF APPLICATION	TIMELINE RELEASED (days)	TIMELINE REQUESTED (days)
4	Endorsement of additional product on registration	120	30
5	Rule 37 and Neutral Code	60	30
6(a)	NOC for Form 29 (Biological and Medical Devices) (if inspection is not involved for grant of NOC)	60	30
6(b)	NOC for Form 29 (Biological and Medical Devices) (if inspection is involved for grant of NOC)	-	90
7	CLAA in Form 28/2B-D-280-E/27-C etc	60	60
8	Import License in Form 10	45	30
9	Test License in Form 10	45	15
10	BA/BE NOC	45	30
11	Extension of Shelf Life for export	45	30
12	Export of Biological samples (after obtaining BA/BE NOC)	45	15
13	Registration of Cosmetics	90	60
14	Registration of Ethics Committee	100	30
15	Post approval changes (major) subjected to clearance of CDL, NDAC	180	60
16	Post approval (minor)	90	30
17	BA/BE Site approval (after receipt of Joint Inspection report)	60	30
18	Issue of Written Confirmation as per EU Directives	30	30

We request you to consider our suggestions, for smoother and tight-time bound functioning of the Pharma sector.

Thanking you

S V VEERRAMANI
President

DR R K SANGHAVI
Chairman, Medical Sub-committee