

DCG(I) / Misc. / 2016 – (56)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi

Dated: 26-05-16

Office Order

In order to streamline the processing of applications for grant of license, approval, permission etc., in partial modification of earlier office order no. DCG(I)/Misc./15/2013-DC dated 10.04.2015 and other related orders, it has been decided that the applications relating to following categories of functions shall be processed and disposed of at the level as under:

Category of Function	Matter to be processed and submitted by the concerned ADC(I) / DDC(I) as per existing channel of submission directly to DCG(I) for disposal.	Matter to be processed and submitted by the concerned ADC(I) / DDC(I) as per existing channel of submission to JDC(I) for disposal.
Import of drugs	Applications for grant of Registration Certificate.	Applications for Import License, amendment, post registration approval, and other related activities.
Medical devices	Applications for grant of permission for clinical trial, Manufacturing / import permission in Form 46 / Form 45, Import Registration and License under CLAA.	Applications for Import License, Test License, amendments, post registration/permission approval, and other related activities.
New Drugs & Clinical Trials	Applications for grant of permission for clinical trial & BA/BE study, Ethics Committee Registration, Manufacturing / Import permission in Form 46 / Form 46A / Form 45 / Form 45A, SAEs and compensation matters.	Applications for Test License, protocol amendments, post registration approval changes and other related activities.
Biological products including Vaccines and r-DNA products	Applications for grant of permission for clinical Trial, Manufacturing / Import permission in Form 46 / Form 46A / Form 45 / Form 45A, Import Registration and Licence under CLAA.	Applications for Import License, Test License, protocol amendments, post registration approval changes, and other related activities.
Blood Banks	Applications for grant of licence to operate Blood bank, Blood products and Blood components.	Post approval changes and other related activities.

The DDC(I) will be supported by concerned ADC(I)s / DIs / ADIs as per the existing arrangement. This shall come in force with immediate effect.


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

To

All JDC(I)s/DDC(I)s/ADC(I)s of CDSCO(HQ)

Copy for information:-

1. PPS to Secretary / PPS to DGHS / PPS to AS(F&D) / PS to JS(R)
2. Director (Admin), CDSCO(HQ)
3. Guard File