DCGI/MISC/2017 (51)
Directorate General of Health Services
Central Drugs Standard Control Organisation
Office of DCG (I)

FDA Bhawan,
Kotla Road, New Delhi- 110002

16th May, 2017.

Dear Colleagues,

As all of you are aware, in terms of the existing provisions of the Drugs and Cosmetics Acts and thereunder Rules relating to new drug approval, as defined in Rule 122(E), prior approval of the Licensing Authority defined under Rule 21(b) is required before granting licence for manufacture for sale or distribution by the State Licensing Authority.

2. Instructions have been issued from time to time to ensure that in all cases regarding approval as new drugs including FDCs, the law/rules should be followed meticulously. Drug regulators of some of the manufacturing States have complained that the licensing authorities of certain States and UTs continue to grant licenses for manufacture of new drugs including FDCs without prior approval of the DCG (I).

3. Since, the practice as indicated above, if true, is illegal and not in conformity with the law and would have disastrous consequences, may I request you to ensure that this practice be stopped forthwith, if it has not already been discontinued. I would also strongly urge you to ensure that any such licences issued may also be cancelled and a report sent to me at the earliest possible.

Yours faithfully

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

ALL DRUG CONTROLLERS OF STATES/UTS