File No. 12-01/14-DC (Pt. 47)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110002

Dated 10.11.2015

**CIRCULAR**

**Subject:-** Issues regarding need for removing the practice of repetition of preclinical/toxicological studies of new drug – regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards issues of repetition of preclinical/toxicological studies, the recommendation of IND Committee and DTAB were noted in the meeting that if a new drug was already approved outside India after conducting pre-clinical/ toxicological studies on animals, such studies are not required to be repeated while approving their proposal for import/ manufacture in India unless there were specific concerns. The concerns, however, needed to be recorded in writing.

This is communicated for information and necessary compliance by all concerned.

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

To:-

i) All stakeholders through website of DCG (I).
ii) Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).

Copy to:-

i) PS to Secretary, Ministry of Health and Family Welfare
ii) PPS to DGHS,
iii) PPS to JS(R).