File no. DCG (I)/Misc/2014 (41-pt-1)
Directorate General of Health Services
Central Drugs Standard Control Organisation
Office of Drugs Controller General India

FDA Bhawan, Kotla road,
New Delhi.

Date: 25 JUL 2014

To

All State/UTs Drugs Controller

Subject: Clarification on Form 29 for the manufacture of clinical trial material-regarding.

Sir,

Kindly refer to this office order Office order No. DCG (I)/Misc/2014 (41) dated 26, March 2014 on the subject cited above. It has been observed that some of the Form 29 license are still being issued with the statement as "Not for clinical trial". It may be mentioned again that the license to manufacture of drugs for the purpose of examination, test or analysis (Form 29) under Rule 89 of the Drugs and Cosmetics Act 1940 and Rules thereunder for various exhibit batches manufactured under GMP environment (tenets of GMP as per Revised Schedule M) are not meant for commercial use or marketing activities but said batches may be used for clinical trial purpose whereas R&D batches manufactured under uncontrolled GMP environment are not meant for clinical trial purpose/commercial use but may be used for test or analysis.

In view of above, it is requested that Form-29 issued by State Licensing Authorities (SLAs) may have a statement as "Not for clinical trials unless otherwise permitted by the Licensing Authority" in place of "Not for clinical trials". In case you require any further clarification you may write to this office.

Yours faithfully,

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

Copy with a request to follow up the issue with State Drugs Controllers to:
All Officers of CDSCO HQ/Zonal/Sub-zonal offices of CDSCO.