File No: X-11026/143/16-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

Dated: 20/12/2016

OFFICE MEMORANDUM

Subject: Issue of clinical trial permission for r-DNA derived products- Regarding

In continuation to this office memorandum dated 13.12.2016, in order to streamline the process of approval of clinical trials of r-DNA products, it has been decided that parallel submission to CDSCO for clinical trials in human, while the Review Committee of Gene Manipulation (RCGM) review is under process will be accepted by CDSCO & if the protocols are found satisfactory after evaluation as per the procedures of CDSCO under the Drugs and Cosmetics rules, the permission to conduct clinical trial will be issued with the condition that the clinical trial should be initiated after RCGM clearance is obtained on the report of preclinical studies.

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

To:

1. JDC(I)/DDC(I)/ADC(I) of Biological Division

Copy to: Stakeholders through CDSCO website for information