FORM 18
RECOMMENDATION OF rDNA PRODUCT(S) FOR HEALTHCARE USE TO DCG(I) FOR THE APPROPRITE PHASE OF CLINICAL TRIAL

PERMIT NUMBER: **DATE OF ISSUE:**

To

The Drug Controller General of India,
C.H.E.B.Campus, FDA Bhawan,
Kotla Road, New Delhi – 110 002.

Subject: ----------

M/s._____, was granted permission vide letter dated _____ to conduct preclinical safety studies on _____on the premises located at_____. It is informed that reports on pre clinical safety studies on _____ were evaluated by the Review Committee on Genetic Manipulation (RCGM) in its meeting held on _____.

Based on the submissions made by the applicant and the recommendations of the RCGM, the applicant has been directed to approach your office for approval to conduct appropriate Phase of human clinical trials on _____ by submitting all relevant information.

Signature & title of issuing officer

(Member Secretary, RCGM)

Copy for information to:

i. The Chairman, GEAC, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodi Road, New Delhi – 110 003
ii. M/s_____ (applicant)
iii. Office copy for file
iv. Guard file

(Member Secretary, RCGM)