FORM C6

RECOMMENDATION OF rDNA PRODUCT(S) FOR HEALTHCARE USE TO DCG(I) FOR THE APPROPRIATE 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.

Kindly acknowledge the receipt of the same

(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