FORM C5

FORMAT FOR SUBMISSION OF PRECLINICAL OR OTHER SAFETY STUDIES REPORT OF rDNA PRODUCTS DEVELOPED USING GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR HEALTHCARE, INDUSTRIAL OR ANY OTHER USE

1. **Name of the Applicant**:

   Designation:

   Address:

   Telephone No.:

   Fax No.:

   e-mail:

2. **DBT Office Memorandum No.:**

3. **Objectives of the proposal:**

4. **Summary of the products characteristics and process of development:**

5. **List of preclinical study protocols approved by RCGM:**
   (please attach a copy of the approval letter)

6. Preclinical study reports:

6.1 List of studies completed and deviations, if any from the approved protocols

6.2 Dose calculation for conduct of safety studies

6.3 Study reports (Each study report would reflect all the issues approved in the protocols). In addition the following to be included:

- RCGM approval of protocol

- IBSC approval of report

- IAEC approval for animal use and for the procedures

- Individual animal data, summary data and any other data like computer analysis outputs etc

- Conclusion

6.4 Address and accreditation status of the labs where these studies were conducted.

7. Measures taken for containment:

8. Decontamination and disposal mechanisms:

9. Risk management (Emergency plan):

10. Any other relevant information:

11. Declaration:
I declare that the information provided in the above format is correct and accurate to the best of my knowledge.

Date: **Signature of the Applicant**

Forwarded:

The proposal set out above has been considered and approved by the "Institutional Biosafety Committee" in its meeting held on and is forwarded to RCGM for further necessary action.

Date: **Signature and name of the Chairman, IBSC**

Note:

1. Please submit 23 copies of the application along with the enclosures to the Member Secretary, RCGM, Department of Biotechnology for consideration by RCGM.
2. Enclosures should include
    - Copies of earlier approvals from RCGM
    - Copy of the minutes of IBSC meeting in which the proposal was approved