Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of the 5th Meeting of the Genetic Engineering Approval Committee held on 23.12.1991 at 2.00 P.M.

The 5th Meeting of the Genetic Engineering Approval Committee (GEAC) was held under the chairmanship of Shri A. Bhattacharjya, Additional Secretary (B) on 23.12.1991 at 2.00 pm. Dr. Sandip K. Basu, Director, National Institute of Immunology and Co-Chairman GEAC was also present. List of participant is given as per Annex. I. Dr. P.K. Gosh, Director, Department of Biotechnology also attended the meeting as special invitee as permissible under Rules for the Manufacture, Use, import, Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or cells, 1989.

Agenda Item No. I: Finalization of Check – list

2. Welcoming the members, the Chairman appreciated the efforts made by Co-chairman and members of GEAC to provide the input for check-lists for appraisal of proposals based on hazardous micro-organisms/recombinant products. The suggestions given by experts on check-lists were discussed and draft check-lists were approved with slight modifications. Revised check-lists are given at Annex II and III.

3. On the suggestion of DBT to have a check-list for transgenic plants, it was decided that a small Expert Committee of plant molecular biologists would be formed, for transgenic plants, pests and pathogens. Dr. Sandip K. Basu was requested to suggest the names of the experts.

4. The meeting was thereafter conducted by the Co- chairman as Chairman had to go out to attend to urgent work.

Agenda Item No. II: Import/Clinical Trials of Recombinant Human Erythropoietin (EPO) for Direct Application in Humans

5. The information supplied by M/s Hindustan Antibiotics Ltd., Pune on EPO was examined by GEAC. It was decided that the firm should provide:

(i) Information relating to the fact that the product has been tested for SV 40 derived material and that the product does not contains any SV 40 genomic material.

(ii) A certificate that the testing is done and conforms to FDA/WHO guidelines for the adventitious material in the product and countersigned by the Managing Director of the Company.

(iii) There should be and undertaking that disposal of wastes, and left over will be as per the DBT guidelines.

(iv) The Gel Electrophoresis map (PH-2) should provide the Molecular weight of the markers from top to bottom.

5. Once the information is furnished, Co-chairman may kindly examine the documents and advice GEAC for further action.

Agenda Item No. III: Marketing of Human Recombinant Interferon alpha-2 B Eye Drops, Cream and Nasal Spray

6. The supplementary material furnished by M/s CIMMCO, Delhi was scrutinized by GEAC. The committee desired that the firm should provide evidence that the test results conform to WHO guidelines on interferon. Since varied results are seen on quality specification certificates of the pure final bulk, the firm should provides to GEAC:

(i) Acceptance range certificate by Cuban Government authorised for quality control and

(ii) Validity of test results and the evidence that they conform to WHO standards for r- interferon.

7. The firm should provide proper label for the product to dispel the concern that three percent innocuous material does not pose any adverse effect.

Agenda Item No. IV: Clearance for import of Recombinant Human Gamma Interferon for use in ICMR Research Project of Kala Azar

8. The case was discussed with the project Coordinator and it was decided that:

(i) there should be and undertaking on safe disposal of wastes generated during experiments: and

(ii) When the material is imported, the certificate of clearance on product quality on each batch of shipment should follow.

9. Once the information is furnished, Co-chairman may kindly examine the documents and advice GEAC for further action.

The meeting ended with a vote of thanks to chairman.

Annex- I

List of Participants

1. Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests, New Delhi.

2. Dr. Sandip. K. Basu, Director, National Institute of Immunology Delhi.

3. Dr. B.B. Mallick, Joint Director (Research), Department of Biotechnology, New Delhi.

4. Dr. K. Narayanaswami, Director, Department of Biotechnology, New Delhi.

5. Dr. P.K.Gosh, Director, Department, Department of Biotechnology, New Delhi.

6. D r. Y.P. Kakar, Director, Ministry of Environment and Forests, New Delhi.

7. Dr. P. Dasgupta, Dy. Drug Controller of India (New Drugs), representative of DGHS, New Delhi.

8. Dr. D. Kanungo, Medical toxicologist, Directorates of Plant Protection, Quarantine and Storage, Faridabad.

9. Dr. (Mrs.) S. Kulshrestha, Sr. Pharmacologist (Medical) Directorate of Plant Protection, Quarantine and Storage, Faridabad.

10. Dr. S.K. Ghosh, Senior scientist, Central Pollution Control Board, Delhi.

11. Dr. Sulbha Gupta, Department of Science and Technology, New Delhi.

12. Dr. R.R. Khan, Additional Director, Ministry of Environment and Forests, New Delhi.

13. Dr. Indrani Chandrasekharan, Scientist 'SE', Ministry of Environment and Forests, New Delhi.

****