Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 17th Meeting of the Genetic Engineering Approval Committee held on 18.08.1998.

****

The 17th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 18.08.1998 under the Chairmanship of Shri Vinod Vaish, Special Secretary in the Ministry. The following officers participated in the meeting.

1. Shri Vinod Vaish, Special Secretary, MOEF, New Delhi- Chairman
2. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow (U.P.)-Co-Chairman
3. Shri Vijay Sharma Joint Secretary, MOEF, New Delhi.
4. Shri S.K. Tondon, Assistant DCGI, New Delhi
5. Prof. Subash Chandra, Department of Biochemical Engineering, Indian Institute of Technology, New Delhi.
6. Shri T. Ramasubramaniam, Industrial Advisor, Ministry of Industries, Department of Industrial Policy and Promotion, Udyog Bhawan, New Delhi.
7. Shri Gajraj Singh, Development Officer, Ministry of Industries, Udyog Bhawan, New Delhi.
8. Shri M.A. Patil, Sr. Deputy Director, National Productivity Council, New Delhi.
9. Shri R.C. Saxena, Environment Engineer, Central Pollution Council, New Delhi.
10. Dr. (Mrs.) S. Kulshrestha, Medical Toxicologist, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
11. D r. R.R Khan, Director, Ministry of Environment and Forests, New Delhi.
12. Ms. Madhu Gupta, Research Assistant, MOEF, New Delhi.

2. Chairman welcomes the participants and referred to minutes of the Sixteenth Meeting of GEAC held on 8th May 1998. The minutes were earli circulated to all the member. Since no comments have been received on the minutes of Sixteenth meeting these were confirmed. Thereafter, various applications as mentioned in the agenda Notes were taken up for discussion.

Manufacture and Export of Recombinant Hepatitis B Surface Antigen Protein by M/s Transgene Vaccine Ltd. Hyderabad

3. This proposal is regarding the manufacture and export of recombinant Hepatitis B surface antigen to be produced at their facility at Hyderabad. Clinical trials have been done only at Korea and Argentina. The representative of DCGI mentioned that recently the firm has submitted the results of Phase-III clinical trials. DCGI was requested to send their comments on the results of clinical trials conducted by the firm. Co-chairman observed that the application appears to be incomplete. It was decided that complete application be placed before GEAC with additional data along with comments from DCGI for consideration of GEAC.

Manufacture of Erythropoietin by M/s Wockhardt Ltd., Mumbai

&

Manufacture of bulk recombinant Hepatitis B formulated Vaccine by M/s Wockhardt Rhein Biopharm Pvt. Ltd. Mumbai.

4. Member Secretary GEAC informed that the above two applications have been submitted by M/s Wockhardt Ltd., Bombay. The firm has requested the Ministry to defer the applications so that the missing information could be submitted to the Ministry. It was decided that once the firm gives complete data on clinical trials and sero conversion studies on human subject, the application may again be submitted to GEAC for consideration.

Import EPREX prefilled syringes containing 500, 1000 and 3000 iv of Recombinant Human Erythropoietin submitted by M/s Johnson and Johnson Ltd., Bombay

5. The proposal submitted by M/s Johnson and Johnson Ltd., Bombay was discussed. It was pointed that the proposal was sent to DBT for comments. Since DBT has requested the firm to supply additional information and the same has not been provided by the firm, it was decided to give one month time to the Applicant to enable them to submit required data. In case, no data are submitted by this date, the application shall be rejected.

Manufacture of Recombinant Hepatitis B Surface Protein by M/s Bharat Biotech International Ltd., Hyderabad.

6. M/s Bharat Biotech International Ltd. Hyderabad has submitted an application for seeking environmental approval for the manufacture of six million doses of recombinant Hepatitis surface protein at their facility at Hyderabad. The firm has already conducted Phase II and III clinical trials, the results of which have been submitted to DCGI. The clinical trial data have been evaluated based on which DCGI proposed to send a Joint Inspection Team comprising of DCGI and State Drug Inspector to inspect the facility. Member Secretary, GEAC informed that a similar proposal using yeast strains namely Sacchoromyces cervisiae as a host for developing vaccine by M/s Shanta Biotech, Hyderabad was earlier approved by GEAC with certain conditions.

7. The comments from DBT have also been received. DBT has recommended the project with the following conditions:

(a) The nucleic acid content in the bulk from all sources should be less than 20 pcg per dose of 20 mcg measured by southern blot DNA hybridization method.

(b) HBsAg content in bulk recombinant protein should be more than 98% as determined by standard method of assay.

(c) The carbohydrate content per dose 20 mcg should be less than 0.01mg as determined by standard protocols.

8. Professor Subash Chandra of IIT, Delhi mentioned that proper effluent treatment measures need to be taken by the firm. IT was pointed out that the firm has already submitted a consent letter from State Pollution Control Board.

9. It was decided that the application may be approved subject to approval by the Drug Controller General of India after the submission of report by the Joint Inspection Team, as well as subject to other conditions as proposed by DBT.

Other Pending Proposals

10. A list of five pending proposals was discussed by the Committee. Chairman mentioned that these are incomplete proposals and experts are unable to evaluate them for want of necessary information. The firms have not responded inspite of several reminders. It was decided that the applicants be given a deadline of one month. The proposals shall be rejected if the firms fail to submit the information within that period.

The meeting ended with a vote of thanks to the Chair.