

**MINUTES OF THE XX MEETING OF COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA) HELD ON 19.7.2007 AT 11.00 A.M. UNDER THE CHAIRMANSHIP OF SHRI B.S. PARSHEERA, CHAIRMAN, CPCSEA AND ADDITIONAL SECRETARY, MINISTRY OF ENVIRONMENT & FORESTS**

A List of Members who attended the meeting and list of Members granted leave of absence is enclosed.

Chairman, CPCSEA, welcomed the members and agenda items were taken up as follows:

**20.1 CONFIRMATION OF THE MINUTES OF THE XIX MEETING OF CPCSEA HELD ON 21<sup>ST</sup> MAY 2007.**

The Committee confirmed the Minutes of the XIX Meeting held on 21<sup>st</sup> May 2007.

**20.2 TO REVIEW THE ACTION TAKEN ON THE MINUTES OF THE XIX MEETING AND PENDING POINTS OF PREVIOUS MEETINGS OF CPCSEA.**

**9.2-3.1.2 Review of experiments using animals in case of traditional medicine**

**9.2-3.2.5 Funding of projects on traditional system of medicine and proper scientific review with regard to the scope and purpose of research.**

A team from AYUSH made a detailed presentation before the members of the Committee on the issue of traditional system of medicine. The members of the Committee raised few queries regarding toxicological studies carried out in respect of the medicines / substances used in traditional system of medicine. It was explained by the team members that 20 research programmes are already in progress on this aspect. However, it was decided by the Chairman that members of CPCSEA may furnish their comments/suggestion on this presentation and a draft note/letter be prepared after inclusion of suggestions/comments for the consideration in the next meeting before it is sent to the AYUSH.

**13.6 Deposit of the amount collected as registration/renewal fee**

The Committee was informed that the matter on the said issue is still under consideration in the Ministry of Expenditure.

### **13.7 Meeting of the Sub-Committee on Rehabilitation on Animals after their Experimentation and Supplementary agenda item No.2**

The Committee noted that few responses have been received and still some of the organizations could not furnish their comments on the issue hence it was agreed in principal to wait for further 6 weeks for comments.

### **16.6.2 Action to be taken on the basis of Report of Consultative Group on Review of the Norms and practices for Regulation of Animal Experimentation**

The Committee accepted Dr. P. Balakrishnamurthy's request for further four weeks time to complete his report.

### **16.8 Approval of Animal House Facility by CPCSEA**

(a) The Committee accepted the suggestion made by Chairman, CPCSEA that any items relating to previous meetings, which were placed for approval of CPCSEA, should also be included as distinct agenda items in the agenda of future meetings.

Noted.

(b) Animal House Facility of VELS College of Pharmacy, Chennai has been approved and hence no action.

Noted.

**17.5 (a)** In respect of Medical Education Department, Stanley Medical College, Chennai, Tamil Nadu.

The Animal House Facilities were approved for the purpose of Experimentation of the animals namely: Rat, Mice and Rabbit.

(b) In respect of Southern Regional Research Centre, Central Sheep and Wool Research Institute, Tamil Nadu.

The Committee noted that re-inspection of the Animal House Facilities of the institute to be done at the earliest by the Expert Consultant CPCSEA in respect all the Centres under the Institute and the proposal for approval of animal house facilities be submitted to CPCSEA thereafter.

(c) The Committee noted that reminder would be sent for the compliance report in respect of the Institute of Veterinary Biology Products, Department of Animal Husbandry, Pune.

**17.6 Proposal of Forest Department, Govt. of NCT of Delhi for use of commensal monkeys being rehabilitated at their monkey shelter at Rajokari for research purposes.**

The Committee was informed that no response had been received from NCT, New Delhi inspite of several reminders. It was agreed that Chairman, CPCSEA would write to Secretary, Environment, N.C.T. of Delhi.

**17.7 Sub-Committee for Selection of CPCSEA Nominees on Institutional Animal Ethics Committees.**

The Committee noted that all the members have already received the guidelines from Prof. A.J. Rao and the same would be considered in the next meeting.

**18.4 Consideration of New Proposals**

The Committee approved the Form-B with following modifications as suggested by Members:

**Part B:**

Sl. No. 2. Qualifications mentioned may be deleted.

Sl. No. 6. Detailed study plan may be given (Not more than one page)

**Investigator's declaration:**

Sl. No. 2. I certify that, I am qualified and have experience in the experimentation on animals.

**18.5 Approval of Animal House Facility by CPCSEA**

(a) The Committee considered the reply furnished by the Dean, Veterinary College, University Agricultural Science, Hebbal, Bangalore and opined that compliance report should be submitted by the institute at the earliest.

(b) The Committee noted the status and suggested that a reminder should be sent to PGIMER, Chandigarh for submission of compliance report.

**18.6 Financial Assistance for Conduct of International Conference on Alternatives to Animal Studies and In Vitro Studies**

The Committee noted the status.

### 19.3 REGISTRATION OF INSTITUTES WITH CPCSEA

The Committee noted that 1059 institutions have been registered with CPCSEA. However it took a serious note that many educational institutions / organizations involving in the animal experimentation are not taking the required permission and decided that an advertisement would be published in the National News Papers in English and Hindi and National Journals (Current Science, Journal of Bombay Natural History Society, Indian Forester). The draft advertisement would be prepared by CPCSEA and would be circulated to all the members for comments thereon.

### 19.4 CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.

#### 19.4.1 Update regarding proposals submitted earlier.

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| 19.4.1 | Update regarding proposals submitted earlier.<br><br>M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Mr. V. D. Pawar, M. Pharm. | In the meeting of CPCSEA held on 20.3.2007, the following project proposal was deferred for want of details regarding the project and was resubmitted for consideration on receipt of clarifications.<br><br>The Institute has submitted the details of Code Numbers of NCE's, bearing code numbers ZYH7 and ZYD1<br><br>Approved | The remarks of committee was conveyed to Director, Cadila Health Care Ltd on 4.6.2007.<br>. |
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| <p><b>19.4.2</b></p> | <p><b>CONSIDERATION OF NEW PROPOSALS:</b></p> <p>1. M/s. Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat). / Dr. M. R. Marathe<br/>Received on 23.3.2007</p> <p>DRF and one month Oral toxicity of NCE in Beagle Dogs (Project code: 10712408)</p> | <p>The Committee noted that no details had been provided regarding frequency of bleeding of the animals and the size of the blood sample to be drawn.</p> <p>The Committee expressed dissatisfaction as the complete details had not been provided in the proposal and stated that the IAEC should have scrutinized the proposal carefully.</p> <p>In particular, the IAEC nominee should be advised to take due care in this regard.</p> | <p>The remarks of Committee was conveyed to Director, Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat) on 4.6.2007.</p> <p>Accordingly, clarifications have been furnished by the Institute and the same are being placed at <b>Agenda Item No. 20.4.1.2</b></p> <p>The CPCSEA Nominee Ms. Snehal Bhatt, Gujarat was also advised to take due care at the time of scrutiny of the proposals and ensure that the proposals should have complete details.</p> |
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| 2. | <p>M/s. Cadila Health Care Ltd.<br/>Zydus Tower,<br/>Satellite Road,<br/>Ahmedabad-380 015.<br/>/Mr. Harilal Patel<br/>Received on 3.5.2007</p> <p>Pharmacokinetic study of new molecules and In-vivo release study of novel formulation in dogs.</p> | <p>The Committee noted that the proposal indicated that the pharmacokinetic profile had been observed to be inconsistent in case of rodents.</p> <p>Accordingly, the rationale for further testing in beagle dogs should be clarified in detail before the proposal could be considered by CPCSEA.</p> <p>In particular the code numbers of the 5 NCEs and the purpose for use of the particular NCEs had not been provided.</p> <p>NCEs used in the earlier rodent studies and details of the pharmacokinetic data were also required for further consideration of the proposal by CPCSEA.</p> | <p>The remarks of committee was conveyed to Director, Cadila Health Care Ltd on 4.6.2007 with the request necessary action/clarification in the light of the observations made by the Committee may kindly be furnished urgently.</p> <p>Accordingly, clarifications have been furnished by the Institute and the same are being placed at <b>Agenda Item No. 20.4.1.1</b></p> |
| 3. | <p>Tamil Nadu Veterinary and Animal Sciences University (TANUVAS),<br/>Madhavaram Milk Colony, Chennai – 600 051/ Dr. N. Daniel Joy Chandran</p> <p>Efficacy of TSU (Ayurvedic product) against Peste des petits ruminants</p>                        | <p>CPCSEA noted that neither details/specification of the Ayurvedic Drug nor the rationale for its use had been given. The IAEC report was not enclosed with the proposal and the parameters for evaluation were not clear. The Committee pointed out the virus-infected animals could not be rehabilitated and should be euthanised. <b>The proposal was not approved</b> by CPCSEA.</p>   | <p>The remarks of committee were conveyed to Director, Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Madhavaram Milk Colony, Chennai on 4.6.2007.</p>  |

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|    | <p>General Observations of CPCSEA regarding proposals received from NDRI, Karnal;</p>   | <p>(i) It was noted that the proposals received from NDRI in many cases did not contain the relevant particulars as per prescribed formats.</p> <p>(ii) The detailed rationale for the studies or justification for research had not been provided.</p> <p>(iii) The IAEC approvals were not accompanied by the requisite tables and it appeared that the IAEC was not examining the proposals carefully.</p> <p>The Committee decided that a letter be addressed to Director, NDRI, Karnal recommending that the Chairman of the IAEC should be at least of the level of Joint Director.</p> <p>(iv) The Committee also recommended that the CPCSEA nominees on the IAEC of the Institution be changed.</p> | <p>Remarks of the Committee were conveyed to the Director, NDRI, Karnal on 15.6.2007 (<b>Pg. No. 59-62</b>) but clarifications / compliance report is not received till date.</p> <p>New Nominees has been appointed on 11<sup>th</sup> June, 2007</p> <p>(i) Dr. Ravindra Sharma, C-7, MCD Officers Flats, R Block, Greter Kailash – I, New Delhi -48</p> <p>(ii) Shri.S. Jayaraman, Institute of Pathology (ICMR) Safdarjang Hospital, Campus, Post Box No.4909 New Delhi – 110 029</p> <p><b>F.No.25/8/2007-AWD</b></p> |
| 4. | <p>N. D. R. I, Karnal, Haryana-132 001. / Dr. S.S. Thakur</p> <p>Nutrient utilization for growth in calves fed rations supplemented with bypass fat</p> | <p>The Committee directed that the proposal be re-submitted after providing the IAEC table and detailed justification for the study.</p>   | <p>The remarks of Committee were conveyed to the Director, NDRI on 15.6.07. The revised proposal has not been submitted till date.</p>   |

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| 5. | N. D. R. I, Karnal,<br>Haryana-132 001. /<br>Dr. R.C. Chopra<br><br>Effect of sun drying<br>of aflatoxin<br>contaminated feed on<br>growth and certain<br>blood parameters in<br>calves  | <b>Approved.</b>   | The remarks of Committee was<br>conveyed to the Director, NDRI,<br>Karnal on 15.6.07.  |
| 6. | N. D. R. I, Karnal,<br>Haryana-132 001. /<br>Dr. Aruna Chhabra<br><br>Status of certain<br>contaminants in<br>animal feeds and<br>measures to minimize<br>their carry over to<br>milk in goats   | CPCSEA did <b>not approve</b> the<br>proposal as no background<br>information had been provided<br>regarding the use of the specific<br>drug in the study. | The remarks of Committee were<br>conveyed to the Director, NDRI,<br>Karnal on 15.6.07. |
| 7. | National Dairy<br>Research Institute,<br>Karnal,<br>Haryana-132 001. /<br>Dr. K.K. Singhal<br><br>Effect of feeding<br>cottonseed produced<br>from Bt cotton<br>cultivar on feed<br>intake, production<br>and composition on<br>milk in dairy cows | The proposal was <b>not<br/>approved</b> by CPCSEA as it<br>involved use of transgenic<br>material requiring appropriate<br>clearances.                    | The remarks of Committee were<br>conveyed to the Director, NDRI,<br>Karnal on 15.6.07. |

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| 8.  | <p>National Dairy Research Institute, Karnal, Haryana-132 001./ Head, DCN Division</p> <p>Drawing the rumen liquor from the rumen fistulated animals for practical classes of M.V.Sc., and Ph.D., Students</p> | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 9.  | <p>National Dairy Research Institute, Karnal, Haryana-132 001./ Dr. S.K. Sirohi</p> <p>Impact of fibrolytic enzymes on nutrient digestibility and growth in buffalo and cattle calves</p>                      | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 10. | <p>National Dairy Research Institute, Karnal, Haryana-132 001./ Dr. S.K. Sirohi</p> <p>Effects of rumensin on methanogenesis, nutrient utilization and milk production in lactating cows.</p>                  | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |

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| 11. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001./<br/>Dr. Amit Kumar<br/>Srivastava</p> <p>Studies on Symbiotic<br/>supplementation on<br/>growth and health<br/>status of crossbred<br/>calves</p>                                 | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 12. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001./<br/>Mr. Hilal Musadiq<br/>Khan</p> <p>Prepartum and<br/>postpartum<br/>management<br/>intervention for<br/>improving<br/>reproductive<br/>performance in<br/>Murrah buffaloes</p> | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 13. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001./<br/>Mr. Raj Kumar<br/>Meena</p> <p>Managemental<br/>intervention for<br/>reducing age at<br/>sexual maturity in<br/>Sahiwal heifers</p>   | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |

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| 14. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001./<br/>Dr. P.K. Nagpal</p> <p>Studies on Growth and Production Performance of Kids and Crossbred Goats under Different Shelter Systems</p>   | CPCSEA did <b>not approve</b> the proposal as no details regarding justification of such a study had been provided. | The remarks of Committee were conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 15. | <p>National Dairy Research Institute,<br/>Karnal,<br/>Haryana-132 001. /<br/>Dr. Shiv Prasad</p> <p>Studies on soya-maize based milk replacer and ruminal fluid inoculation on productive performance of crossbred calves</p>  | <b>Approved.</b>  | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07.  |
| 16. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Mr. Riaz Ahmad Shah</p> <p>Establishment of electrofusion procedure and culture conditions for production of handmade cloned embryos in Buffalo (<i>Bubalus bubalis</i>)</p> | <b>Approved.</b>  | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07.  |

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| 17. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Dr. Prava<br/>Mayengbam</p> <p>Heat Shock Protein<br/>70 Expression in<br/>Relation to<br/>Thermotolerance of<br/>Sahiwal and Sahiwal<br/>x Holstein- Friesian<br/>Crossbred Cattle</p>  | <b>Approved.</b>   | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07.  |
| 18. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Dr. S.N. Rai</p> <p>Studies on Acacia<br/>nilotica pods<br/>replacing energy<br/>sources in ration of<br/>dairy cows on<br/>production<br/>performance and<br/>neutraceutical value<br/>of milk and milk<br/>products</p>      | CPCSEA directed that the proposal should be re-submitted after the testing on rats has been completed. Results of the study on rats should also be provided at the time of resubmission of the proposal. | The remarks of Committee were conveyed to the Director, NDRI, Karnal on 15.6.07. The revised proposal has not been received till date. |
| 19. | <p>National Dairy<br/>Research Institute,<br/>Karnal,<br/>Haryana-132 001. /<br/>Dr. Veena Mani and<br/>Dr. Neelam<br/>Kewalrmani</p> <p>Evaluation of certain<br/>binding<br/>agents/nutrients to<br/>counteract heavy<br/>metal toxicity in<br/>cross-bred<br/>calves/kids</p> | <b>Approved</b>  | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07.  |

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| 20. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Dr. Rajesh Kanna</p> <p>Effects of Body<br/>Condition Score on<br/>metabolic and<br/>oxidative status in<br/>Periparturient cows</p>   | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 21. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Dr. Sanjay Kumar</p> <p>Development and<br/>evaluation of<br/>complete feed block<br/>on low grade<br/>roughage fortified<br/>with potential<br/>anerobic fungi in<br/>buffaloes</p> | <b>Approved.</b> | The remark of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07.  |
| 22. | <p>N. D. R. I, Karnal,<br/>Haryana-132 001. /<br/>Santosh Kumar<br/>Guide, Dr. K.K.<br/>Mehla</p> <p>Effect of herbal feed<br/>supplement Jivanti<br/>(<i>Leptadeni reticulata</i>)<br/>on milk production in<br/>crossbred cattle</p> | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |
| 23. | <p>National Dairy<br/>Research Institute,<br/>Karnal,<br/>Haryana-132 001. /<br/>Dr. K.K. Singhal</p> <p>Optimization of<br/>energy and nitrogen<br/>availability for<br/>microbial protein<br/>synthesis in the<br/>rumen</p>         | <b>Approved.</b> | The remarks of Committee was conveyed to the Director, NDRI, Karnal on 15.6.07. |

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| 24. | <p>Ranbaxy Laboratories Limited<br/>R &amp; D-II, Sarhaul,<br/>Sector-18,<br/>Gurgoan-122 001/<br/>Dr. N. Parthiban</p> <p>Import of Beagle dogs to conduct experiments against approved protocols</p>                                 | <p>CPCSEA directed that clarification regarding the import requirements of beagle dogs be obtained personally by Expert Consultant, CPCSEA along with another official to be nominated by Sr DDG, ICMR. Based on the report the Committee authorized Chairman, CPCSEA to take decision in this regard.</p> | <p>The remarks of Committee were conveyed to the Director, Ranbaxy Laboratories Limited, Gurgaon on 4.6.2007.</p> <p>The proposal was <b>approved</b> with the approval of Chairman, CPCSEA, on the basis of the report submitted by ICMR official and Expert Consultant, CPCSEA, Chennai.</p> <p><b>F.No.25/8/2007-AWD</b></p> |
| 25. | <p>Ranbaxy Laboratories Limited<br/>R &amp; D-II, Sarhaul,<br/>Sector-18,<br/>Gurgoan-122 001/<br/>Dr. Srinivasan M. Rajaram,</p> <p>A sub-acute oral toxicity study of a new chemical entity, NCE (Ketolide class) in Beagle dogs</p> | <p>CPCSEA directed that clarification regarding the import requirements of beagle dogs be obtained personally by Expert Consultant, CPCSEA along with another official to be nominated by Sr DDG, ICMR. Based on the report the Committee authorized Chairman, CPCSEA to take decision in this regard.</p> | <p>The remarks of Committee were conveyed to the Director, Ranbaxy Laboratories Limited, Gurgaon on 4.6.2007.</p> <p>The proposal was approved with the <b>approval</b> of Chairman, CPCSEA, on the basis of the report submitted by ICMR official and Expert Consultant, CPCSEA, Chennai.</p>                                  |
| 26. | <p>Ranbaxy Laboratories Limited<br/>R &amp; D-II, Sarhaul,<br/>Sector-18,<br/>Gurgoan-122 001/<br/>Dr. Srinivasan M. Rajaram,</p> <p>Dose range finding study of a new chemical entity, NCE (Ketolide class) in Beagle dogs</p>        | <p>CPCSEA directed that clarification regarding the import requirements of beagle dogs be obtained personally by Expert Consultant, CPCSEA along with another official to be nominated by Sr DDG, ICMR. Based on the report the Committee authorized Chairman, CPCSEA to take decision in this regard.</p> | <p>The remarks of Committee were conveyed to the Director, Ranbaxy Laboratories Limited, Gurgaon on 4.6.2007.</p> <p>The proposal was approved with the <b>approval</b> of Chairman, CPCSEA, on the basis of the report submitted by ICMR official and Expert Consultant, CPCSEA, Chennai.</p>                                  |

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| 27. | National Institute of Nutrition<br>Jamai Osmania P.O.<br>Hyderabad – 500 007<br>(A.P.)/Dr. P. Suresh<br><br>Pharmacokinetic study of Radiation Protection Drug EX-RADTM ON 1210Na in Monkeys, Macaca mulatta | CPCSEA directed that details of earlier testing on animals below the level of sentience of monkeys should be provided.<br><br>It may also be confirmed as to whether the proposal was in the nature of contract research. | The remarks of Committee were conveyed to the Director, National Institute of Nutrition, Hyderabad – on 4.6.2007 with the request that requisite information may be furnished.<br><br>Accordingly, desired information/details have been furnished by the Institute and the same is being placed at <b>Agenda Item No. 20.4.1.4</b> |
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The Committee noted the status of the above proposals.

**19.5 Permission Sought by Defence Institute of Physiology & Allied Sciences, Delhi for Procurement of Cats.**

The Committee noted the status.

**19.6 APPROVAL OF ANIMAL HOUSE FACILITY BY CPCSEA**

(a).Bharat Serum & vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400604, Maharashtra

The Committee noted the status and suggested that a reminder may be sent to the Institute for submission of compliance Report.

(b) Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad – 387001, Gujarat.

The committee noted that approval is already conveyed to the Institute.

(c) Vetcare Group of Companies, IS-40, KHB Industrial Area, Yelahanka New Town, Bangalore-560064, Karnataka.

The Committee noted the status and suggested that a reminder may be sent to the Organization for submission of compliance Report.

**AGENDA ITEM NO. 20.3 : REGISTRATION OF INSTITUTES WITH CPCSEA.**

The Committee noted that 1068 institutions have been registered with CPCSEA.

**AGENDA ITEM NO. 20.4 : CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.**

**AGENDA ITEM NO.20.4.1: Update regarding proposals submitted earlier.**

In the previous meetings of CPCSEA held on **20.3.2007 & 22.5.2007**, the following project proposals were deferred for want of details regarding the project and was resubmitted for consideration on receipt of clarifications. .

| <b>S. No.</b> | <b>Name of the institute/Name of the Investigator</b>   | <b>Project Title</b>   | <b>Decision of the XX CPCSEA meeting</b>   |
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| 1.            | M/s. Cadila Health Care Ltd.<br>Zydus Tower,<br>Satellite Road,<br>Ahmedabad-380 015. /Mr. V. D. Pawar, M. Pharm.   | Pharmacokinetic study of new molecules and In-vivo release study of novel formulation in dogs. | Approved   |
| 2.            | M/s. Sun Pharma Advanced Research Center (SPARC),<br>Tandalji Vadodara – 390 020 (Gujarat). /<br>Dr. M. R. Marathe<br>Received on<br>23.3.2007  | DRF and one month Oral toxicity of NCE in Beagle Dogs (Project code: 10712408)                 | Approved   |
| 3.            | Sree Chitra Tirunal Institute for Medical Science and Technology,<br>Biomedical Technology Wing (BMT Wing),<br>Poojapura,<br>Thiruvananthapura m-695 012, Kerala /<br>Dr. D.S. Nagesh<br>Received on<br>13.3.2007 | Ex-vivo evaluation of Centrifugal blood pump.<br><br>Species: Sheep                            | The Committee considered the appeal made by the institution regarding request for 15 experiments. The committee observed that there is confusion regarding decision taken in its previous meeting. Hence, institution may be requested to furnish the flow chart of the experiments on Sheeps for further consideration. |

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| 4. | National Institute of Nutrition<br>Jamai Osmania<br>P.O.<br>Hyderabad – 500<br>007 (A.P.)/Dr. P.<br>Suresh<br>Received on<br>8.5.2007 | Pharmacokinetic<br>study of Radiation<br>Protection Drug EX-<br>RADTM ON<br>1210Na in Monkeys,<br>Macaca mulatta | Approved |
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**AGENDA ITEM NO.20.4.2: CONSIDERATION OF NEW PROPOSALS:**

The project proposals placed before the Committee were examined as under:

| S. No | Name of the institute/Name of the Investigator   | Project Title   | Decision of the XX CPCSEA meeting  |
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| 1.    | M/s. Sun Pharma<br>Advanced Research<br>Center (SPARC),<br>Tandalji Vadodara –<br>390 020 (Gujarat)./<br>Dr. M. R. Marathe<br>Received on<br>18.6.2007 | 14 days DRF and repeated dose<br>regulatory toxicity study in<br>Beagle Dogs - (Project code:<br>10711133)<br><br>Species: Beagle Dogs<br><br>Male 4 – 6 months,<br>30nos.<br>Female 4 – 6 months,<br>30nos.<br><br>Objectives : To Characterize the<br>toxicity profile of test item after<br>repeated exposure to Beagle<br>Dogs. | The Committee noted that no<br>details have been provided<br>regarding how many doses<br>required in the experiments<br>and justification for the large<br>number of animals may be<br>provided. |

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| 2. | <p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapura m-695 012, Kerala /Dr. P.R. Umashankar<br/>Received on 18.5.2007</p>  | <p>Animal evaluation of Sahajanand Sirolimus eluting coronary stents in porcine coronary artery model.</p> <p>Species: Pigs (Desi Cross Bred) of 30-60 kg. / Young – Adult.</p> <p>Number to be used : 60 nos.</p> <p>Objectives : To evaluate an indigenously developed Sahajanand Sirolimus eluting coronary stents for safety and functional efficacy in pig coronary artery model before actually using it in human patients.</p> | Approved |
| 3. | <p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapura m-695 012, Kerala /Mr. Muraleedharan CV<br/>Received on 18.5.2007</p> | <p>Development of improved tilting disc heart valve prosthesis</p> <p>Species: Pigs (Desi Cross Bred) of 30-60 kg. / Young – Adult.</p> <p>Number to be used : 20</p> <p>Objective : To qualify the device being developed as per international standard ISO 5840 Cardiovascular implants – cardiac valve prosthesis – 2005 (Revised standard).</p>   | Approved |
| 4. | <p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapura m-695 012, Kerala /Mr. Muraleedharan CV<br/>Received on 18.5.2007</p> | <p>“Development of improved tilting disc heart valve prosthesis”.</p> <p>Species: Sheep Male</p> <p>Number to be used : 20</p> <p>Objective : To qualify the device being developed as per international standard ISO 5840 : Cardiovascular implants – cardiac valve prosthesis – 2005 (Revised standard).</p>  | Approved |

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| 5. | <p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapura m-695 012, Kerala /Dr. Prabha D. Nair<br/>Received on 18.5.2007</p> | <p>Islet Immuno Isolation with Xeno Transplantation and Stem Cell Regeneration to Islets as Strategies for Treatment of Diabetes</p> <p>Species: <i>Sus. domesticus</i> – Neonates and 3-4 months, 10-15 kg.</p> <p>Number to be used : 25, 1 per week</p> <p>Objective : To evaluate whether macro capsules made up of this novel polymer can function as immunomodulatory barrier for transplanted xenogenic islet cells in rats, without immunosuppressant drugs.</p> | <p>The Committee considered the proposal in depth and it did not approve the same and suggested that studies be done in lower rodents and there is no need for Pig studies.</p> |
| 6. | <p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapura m-695 012, Kerala /Dr. P.R. Umashankar<br/>Received on 5.7.2007</p> | <p>Biofunctional evaluation of NTU drug eluting coronary stents in porcine coronary artery model.</p> <p>Species : Pigs (Desi Cross Bred) - Young Adult / 30 – 60 kg.</p> <p>No. to be used : 57</p> <p>Objective : To evaluate novel drug eluting coronary stents developed by NTU for safety and functional efficacy in pig coronary artery model before actually using it in human patients.</p>  | <p>Approved</p>   |

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| 7. | Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. S.R. Krishnamanohar Received on 5.7.2007 | Development of de-cellularised animal tissue for cardio-vascular application.<br><br>Species : Sheep – Weight 30 kg and above.<br><br>No. to be used : 10<br><br>Objective : To evaluate processed bovine jugular vein for application as valved conduit between right ventricle and pulmonary artery. | The Committee noted that no details/clarifications provided in this proposal. The source of Bovine Jugular vein may be furnished for further consideration. |
| 8. | M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Mr. V. D. Pawar, M. Pharm.   | To evaluate the effect of ZY12 on cardiovascular system in telemetered dogs.<br><br>Species: Beagle Dogs – 6-24 months and 6-16 kg. weight<br><br>Number to be used : 8<br><br>Objective : Effect of NCEs on cardiovascular system will be evaluated in the telemetered conscious beagle dogs.         | Approved  |

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| 9.  | National Brain Research Centre<br>Naiwal Mode, Near NSG Campus<br>Manesar – 122 050, Haryana. / Dr. Neeraj Jain<br>Received on 08.06.2007                  | The effects of spinal cord and cortical lesions on the brain.<br><br>Species: Macaque<br><br>Number to be used: 48 (8 of these will be new born)<br><br>Objective : (i) What kinds of changes take place in the somatosensory and motor areas of the brain following lesions of the dorsal columns of the spinal cord or small regions of the cortex, (ii) How do these changes relate to changes in the use of the affected hand, (iii) How changes in the brain are different if lesions take place early in development, (iv) What areas of the brain mediate partial recoveries from lesions of the spinal cord and brain, (v) What are the mechanisms of changes in the brain and if any new neuronal growth takes place in the brain. | The committee approved the proposal with the condition that before initiating the project, clearance from the Principal Chief Conservator of Forests (PCCF) may be taken. A copy of the letter would be endorsed to PCCF. |
| 10. | National Brain Research Centre<br>NH-8, Jaipur Highway<br>Nainwal Mode, Manesar, Gurgaon (District), Haryana<br>Dr Aditya Murthy<br>Received on 08.06.2007 | The role of basal ganglia and frontal cortex in control<br><br>(Approved by CPCSEA in XVIIth meeting held on 22.1.2007) and request for minor modification.<br><br>Species: Macaca sp.<br><br>Number to be used: 16   | The committee approved the proposal with the condition that before initiating the project clearance from the Principal Chief Conservator of Forests (PCCF) may be taken. A copy of the letter would be endorsed to PCCF.  |

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| 11. | National Brain Research Centre, Manesar (Gurgaon) Haryana – 122 050 / Mr. Narender K. Dhingra<br>Received on 08.06.2007   | Replacement of Degenerating Retinal Neurons by Stem Cells or by Retinal Prosthesis: A Study on Connectivity and Signal Processing in Retinal Ganglion Cells.<br><br>&<br>Request for permission to use two monkeys of another approved protocol of Dr. Neeraj Jain<br><br>Species: Guinea pig – 450 – Adult ( 400-700 gms.)<br>Mouse (C57BL & - 200 (Adult ( 20-30 gms.) rd mutant) - 300 (E14-P0(2-5 gm) | Approved   |
| 12. | Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow-226 001/Dr. Sharad Sharma<br>Received on 18.6.2007 | 99/411: 28 Days Repeat Dose of Toxicity Study in Monkey by Oral Route<br><br>Species : (a) Rhesus Monkey<br>(b) Adult 4.0 to 6 kg.<br>(c) Male and Female<br>(d) 14 Males and 14 Females<br>(e) 45 Days for quarantine period and 30 days for study. The monkeys will be housed in restraint type cage-run (preferably of size 150cmx75cm) with an area of about 11,000 sq.cm.                            | The committee approved the proposal in principle with a condition that the Animal House Facilities of the institute should already have been approved by CPCSEA. |

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| 13. | <p>Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow-226 001/Dr. D.S. Upadhyay Received on 18.6.2007</p>      | <p>Effect of new feed formulation (CDRI pelleted diet) on the biological and biochemical parameters in rhesus monkeys</p> <p>Species : Rhesus monkeys<br/>No. to be used : 10 animals from rehabilitation unit. After initial one month's caging the animals will be freed and then two days caging for collection of samples and then freeing in the rehabilitation.</p>   | <p>The committee approved the proposal in principle with a condition that the Animal House Facilities of the institute should already been approved by CPCSEA.</p> |
| 14. | <p>Ranbaxy Laboratories Limited., R &amp; D-II, Sarhaul, Sector-18, Gurgaon-122 001/ Dr. N. Parthiban<br/>Received on 9.7.2007</p> | <p>Import of Beagle dogs to conduct Dose range finding and Sub acute oral toxicity study of new chemical entity (NCE-Ketolide class) in beagle dogs.</p> <p>Species : Beagle dogs<br/>No. to be used : (i) Dose range finding study of a new chemical entity (NCE-Ketolide class) in beagle dogs 9M+9F<br/>(ii) A sub-acute oral toxicity study of a new chemical entity, (NCE-Ketolide class) in beagle dogs 16M+16F</p> | <p>Approved</p>  |
| 15. | <p>Ranbaxy Laboratories Limited., R &amp; D-II, Sarhaul, Sector-18, Gurgaon-122 001/ Dr. N. Parthiban<br/>Received on 9.7.2007</p> | <p>Import of Beagle dogs to conduct In vivo evaluation of emetic potential of new chemical entities in the conscious beagle dogs.</p> <p>Species : Beagle dogs<br/>No. to be used : 6 dogs</p> <p>Objective : Animals will be imported for the project entitled "In vivo evaluation of emetic potential of new chemical entities in the conscious beagle dogs".</p>   | <p>Approved</p>  |

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| 16. | <p>Ranbaxy Laboratories Limited.,<br/>R &amp; D-II, Sarhaul, Sector-18, Gurgaon-122 001/ Mr. Pravin J. Patil</p> <p>Received on 9.7.2007</p> | <p>Import of dogs to conduct study for evaluation of effect of New Chemical Entities (NCE) on Blood Pressure, Heart Rate and Electrocardiogram in Conscious Telemetered Dog.</p> <p>Species : Beagle dogs – 10-15 Kg.<br/>No. to be use : 16</p> <p>Objective : To assess the effect of New Chemical Entity (NCE) of MMP 9 &amp; 12 inhibitor, DPPIV inhibitor, PDEIV inhibitor, Ketolide anti-infective and MRA antagonist class on Blood Pressure, heart Rate and Electrocardiogram in the conscious telemeterd dog.</p> | Approved |
| 17. | <p>Ranbaxy Laboratories Limited.,<br/>R &amp; D-II, Sarhaul, Sector-18, Gurgaon-122 001/ Mr. S. Raj Kumar</p> <p>Received on 9.7.2007</p>    | <p>In vivo evaluation of emetic potential of new chemical entities in the conscious beagle dogs.</p> <p>Species : Beagle dogs - 12-16 kg<br/>No. to be used : 6 Dogs<br/>Objective : Bronchial asthma is a complex polygenic allergic disease involving a wide range of cell and mediator types (Barnes, 1998).</p>  | Approved |

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| 18. | Wockhardt Research Centre<br>D-4, MIDC Area, Chikalhana, Aurangabad – 431 210 / Dr. M.B. Nandanwar<br><br>Received on : 9.7.2007 | Pharmacokinetics & Toxicokinetic study of NCE's in Beagle Dog<br><br>Species : Dog Strain : Beagle<br>2-4 years<br><u>No. to be used :</u><br>(i) Pharmacokinetic Study : 8Male & 8 Female<br>(ii) Toxicokinetic Study : 8 Male & 8 Female<br>Objective : To assess the Pharmacokinetics & Toxicokinetics of NCE's for finalizing in vivo efficacy and long-term toxicity dose regimen | The Committee considered the proposal in depth but did not approve the proposal as the code of NCE's has not been provided. |
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**AGENDA ITEM NO. 20.5 : PERMISSION SOUGHT BY SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCE AND TECHNOLOGY, BIOMEDICAL TECHNOLOGY WING (BMT WING), POOJAPURA, THIRUVANANTHAPURAM-695 012 TO SOURCE LOCALLY AVAILABLE DOGS FOR STARTING AN IN-HOUSE BREEDING COLONY TO MEET THEIR REQUIREMENTS FOR EXPERIMENTAL PURPOSES.**

The Committee considered the proposal and approved the same with a condition that details of the local breeds of the dogs which will be used in the breeding colony may be furnished.

**AGENDA ITEM NO. 20.6: APPROVAL OF ANIMAL HOUSE FACILITY BY CPCSEA**

**(a) Indian Veterinary Research Institute, Mukteswar, Kumaon, Nanital - 263 138, Uttarakhand**

The Committee decided that the suggestions/observations made by the Inspection team for improvement of the Animal House Facilities may be sent to the institution for its compliance within six months.

**(b) Central Avian Research Institute, Izatnagar-243 122, Bareilly, Uttar Pradesh**

The Committee decided that the suggestions/observations made by the Inspection team for improvement of the Animal House Facilities may be sent to the institution for its compliance within six months.

**(c) Bharat Serums & Vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400 604, Maharashtra.**

The Animal House Facilities is approved for the purpose of Breeding and Experimentation of the animals namely: Horses and Ponies.

**SUPPLEMENTARY AGENDA ITEM NO. 1.**

| <b>Sl. No</b>      | <b>Name of the institute/Name of the Investigator</b>   | <b>Project Title</b>   | <b>Decision of the XX CPCSEA meeting</b>   |
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| <b>ITEM NO. 1.</b> | Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow – 226 001/Director/Dr. S. Upadhyay | Request for formal permission of CPCSEA for establishment of dog facility for research and testing purposes.   | CPCSEA has no objection to grant permission to establish a dog facility in the Institute as per norms.   |
| <b>ITEM NO. 2.</b> | Animal Welfare Officer – Ms. Anuradha Sawhney & Others  | Commentary on the recommendations of the Sub-Committee on Rehabilitation of Animals after Experimentation. – The commentary sent by the Animal Welfare Officers is photocopy of the comments made by PETA as enclosed in Item No. 13.7 at Pg. No. 42-46 of Agenda. | The Committee noted that few responses have been received and still some of the organizations could not furnish their comments on the issue hence it agreed in principle to wait for further 6 weeks for comments. |

**AGENDA ITEM NO. 20.7: ANY OTHER ITEM WITH PERMISSION OF CHAIRMAN**

The members of the Committee appreciate the pivotal role of Expert Consultants to tackle the issues and work of CPCSEA. Further Committee members were of the opinion that the existing posts of Expert Consultants in CPCSEA which are presently on contractual basis, should be made in the regular pay scale and strength of the Ministry. It will help in strengthening and smooth functioning of CPCSEA. The Chairman, CPCSEA informed the members that present arrangement for appointment of Expert Consultants on contractual basis is according to SFC decision and, however the suggestions will be examined.

The meeting ended with a vote of thanks to Chair.

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Annexure**The following Members were present for the meeting on 19.7.2007**

1. Shri. B.S. Parsheera, Chairman  
Additional Secretary,  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.  
Tel : 24361308  
Fax : 24363967
  
2. Shri. Vivek Saxena,  
Director (AW) & Member-Secretary, CPCSEA  
Ministry of Environment & Forests  
8<sup>th</sup> Floor, Jeevan Prakash Bldg.,  
25, Kasturba Gandhi marg,  
New Delhi – 110001.
  
3. Dr. V.K. Vinayak,  
(Retd.) Senior Advisor),  
Department of Biotechnology,  
B-1, E-12, Mohan Co-Operative Industrial  
Estate, Mathura Road, New Delhi-110 044.
  
4. Dr. Vasantha Muthuswamy,  
Sr. Dy. Director General &  
Chief, Division of BMS, Traditional Medicines & Bioethics,  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi-110 029.
  
5. Dr. P. Balakrishnamurthy,  
Director,  
International Institute of Biotechnology & toxicology (IIBAT),  
12, Harleys Road, Kilpauk,  
Chennai - 600 010.
  
6. Dr. D. Swaroop  
Head, Division of Medicine,  
IVRI, Izatnagar – 243122  
Uttar Pradesh
  
7. Dr. Kondavalla Venkaiah,  
Head & Addl. Director,  
Bio-Statistics Department,  
National Institute of Nutrition,  
Hyderabad-500 007.

8. Dr. K. Nachimuthu,  
Director of Research,  
Tamilnadu Veterinary and Animal Sciences University (TANUVAS),  
No.4, Dhamodara Street, Panchvadi, Chetpet,  
Chennai-600 031.
9. Prof. Anup Kumar Nayak,  
Wildlife Institute of India,  
Post Bag #18, Chandrabani,  
Dehradun – 248 001, Uttaranchal.

**Leave of absence was granted to following:**

1. Shri. G. Balachandhran Vice Chairman  
Joint Secretary (Animal Welfare),  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.
2. Dr. Shashi Motilal,  
Professor (Philosophy),  
University of Delhi,  
7, Vaishali Apartments, IIT/Delhi, Hauz Khas,  
New Delhi-110 016.
3. Prof. A. J. Rao ( Retd),  
Department of Biochemistry,  
Indian Institute of Science,  
Bangalore – 560012.
4. Dr. T.P.R. Bhardwaj,  
Senior Consultant, Haematologist,  
Apollo Hospitals, 21, Greams Lane,  
Off. Greams Road, Chennai-600 006.

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