

**MINUTES OF THE XXI MEETING OF COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA) HELD ON 18.9.2007 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 was granted leave of absence is enclosed.

Chairman, CPCSEA, welcomed the members of the Committee and thereafter with the permission of Chairman, agenda items were taken up as follows:

**AGENDA ITEM NO.21.1 : TO CONFIRM THE MINUTES OF THE TWENTIETH MEETING OF CPCSEA HELD ON 19<sup>th</sup> JULY, 2007.**

The Committee confirmed the Minutes of the XX Meeting held on 19<sup>th</sup> July 2007.

**AGENDA ITEM NO.21.2 : TO REVIEW THE ACTION TAKEN ON THE MINUTES OF THE XX<sup>th</sup> 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.**

The Committee decided that a soft copy of the presentation made by the AYUSH team would be circulated to all CPCSEA members to furnish their comments/suggestions on the same for further consideration. A letter is to be written to "AYUSH", seeking details regarding present provision of registration and protocols.

**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. It was decided that the Member Secretary, CPCSEA may be pursue the matter with Department of Expenditure, Ministry of Finance.

**13.7 Meeting of the Sub-Committee on Rehabilitation on Animals after their Experimentation (along with) Supplementary agenda item No.2)**

The matter was discussed in the Committee and it has decided that all the responses received from various organizations/institutions would be sent to the members of the Rehabilitation Committee for their consideration and final recommendations in the matter. It was agreed, that, for small animals, rehabilitation is not required.

### **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 discussed the guidelines prepared and submitted by Dr. P. Balakrishnamurthy and Dr. K. Nachimuthu, CPCSEA members. However, the Committee was of the opinion that the research proposals that fall under the following categories (excluding wild animals studies) would be approved by the IAEC of institutions/organizations.

1. Feeding trial that do not cause stress and do not involve any invasive procedure but involving measurement on
  - Feed intake
  - water intake
  - body weight
  - body size
  - body condition and score
  - digestibility
  - milk production and milk quality
  - wool production and wool quality
  - egg production and egg quality
  
2. Feeding trial in food animals that do not cause stress and do not involve any invasive procedure and slaughtered in humane way, involving measurement on meat and meat quality.
  
3. Breeding experiments that do not cause stress and do not involve any invasive procedure, involving measurement on
  - litter size (no of off springs)
  - litter weight (weight of off springs)
  - breed characters
  - breed improvement
  - breed preservation
  - reproduction traits
  - production traits
  - age at maturity
  - body measurements
  - feed conversion efficiency
  
4. Livestock/ poultry management studies that do not cause stress and do not involve any invasive procedure, involving measurement on
  - animal behavior
  - animal comfort and health
  - reproduction traits
  - production traits
  
5. Wild animals studies that do not cause stress and do not involve any invasive procedure and without any restraintment, involving measurement on

- animal behavior
- animal comfort and health

The approval of the IAEC of the Institutes/Organizations will subject to the following conditions/regulations:

### **Conditions/ regulations**

The study must be conducted by only trained staff who is familiar with animal care, handling and ethical issues.

A register must be maintained by the Animal house in charge/head of the dept, containing information on names and CVs and training records of scientists/supporting staff who performed the said experiment and dates of study.

A brief outline/ method/ procedure adopted for the study with source, number, sex, and species/ breed of animals employed for the study and the conditions/ husbandry maintained.

Result of each study collected with a copy of publication/ report.

Follow up observations recorded on the animal(s) after completion of said study with information on health status, illness, if any, and procedures of euthanasia/ rehabilitation adopted, if any.

Records of re use of animals, if any, with details of waiting period before new study/ experiment performed.

General conditions and health records of all animals that are used for such studies listed above.

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

(b) In respect of Southern Regional Research Centre, Central Sheep and Wool Research Institute (CSWRI), Tamil Nadu, the Committee decided that the Expert Consultant CPCSEA inspect all the Centres under the Institute and the Inspection Reports of the each Animal House Facilities would be submitted to CPCSEA for its consideration.

(c) In respect of Institute of Veterinary Biology Products, Department of Animal Husbandary, Pune -411 007, Maharashtra, the Committee noted that the compliance report had not yet been submitted and hence a reminder may be sent to the institute for immediate submission of compliance report.

### **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 has been received from NCT, New Delhi inspite of letter from Chairman, CPCSEA. It was suggested that a reminder would be send to Secretary, Environment, NCT, New Delhi by the Vice Chairman, CPCSEA.

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

The Committee approved the following guidelines for future selection of CPCSEA nominee.

1. Must be a graduate preferably in Veterinary Science, Medical Science or any of the Biological Science (Botany, Zoology, Wildlife Biology, Life Sciences, Microbiology, Biotechnology, etc.) with an aptitude and concern for animal welfare.
2. At least 3 to 5 years of involvement in any organizations associated with animal welfare, research and breeding or
3. Experience in any organization using animals as experimental models (any biological laboratories, research institutes, pharmaceutical companies).
4. Should be willing to spare at least 2 to 3 days once in three months to attend the IAEC meetings.
5. Should be able to obtain permission from competent authorities, if employed.

#### **18.4 Consideration of New Proposals**

The Committee approved the modified Form B.

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

(a) In the matter of Veterinary College, University Agricultural Science, Hebbal, Bangalore, the committee took serious note of non submission of compliance report and decided that a show cause notice be issued to the institute.

(b) In the matter of PGIMER, Chandigarh. The committee took serious note of non submission of compliance report and decided that a show cause notice be issued to the institute.

#### **19.3. Registration Of Institutes With CPCSEA**

The Committee decided that the draft advertisement would be prepared by CPCSEA within a week and will be circulated to the all CPCSEA members for their comments/suggestions.

#### **19.6 Approval Of Animal House Facility By CPCSEA**

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

The compliance report on the observations made by the committee in respect of approval of Animal House Facilities of the institute was placed before CPCSEA and it has been decided by the Committee that the decision will be taken after re-inspection by Expert Consultant.

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

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

#### **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>
1.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, 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), Tandalji Vadodara – 390 020 (Gujarat). / Dr. M. R. Marathe Received on 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, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. D.S. Nagesh Received on 13.3.2007	Ex-vivo evaluation of Centrifugal blood pump.  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.
4.	National Institute of Nutrition Jamai Osmania P.O. Hyderabad – 500 007 (A.P.)/Dr. P. Suresh Received on 8.5.2007	Pharmacokinetic study of Radiation Protection Drug EX-RADTM ON 1210Na in Monkeys, Macaca mulatta	Approved

**AGENDA ITEM NO.20.4.2: Consideration Of New Proposals:**

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

<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>
1.	M/s. Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat)./ Dr. M. R. Marathe Received on 18.6.2007	14 days DRF and repeated dose regulatory toxicity study in Beagle Dogs - (Project code: 10711133)  Species: Beagle Dogs  Male 4 – 6 months, 30nos. Female 4 – 6 months, 30nos.  Objectives : To Characterize the toxicity profile of test item after repeated exposure to Beagle Dogs.	The Committee noted that no details have been provided regarding how many doses required in the experiments and justification for the large number of animals may be provided.
2.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. P.R. Umashankar Received on 18.5.2007	Animal evaluation of Sahajanand Sirolimus eluting coronary stents in porcine coronary artery model.  Species: Pigs (Desi Cross Bred) of 30-60 kg. / Young – Adult.  Number to be used : 60 nos.  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.	Approved

3.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Mr. Muraleedharan CV Received on 18.5.2007	Development of improved tilting disc heart valve prosthesis  Species: Pigs (Desi Cross Bred) of 30-60 kg. / Young – Adult.  Number to be used : 20  Objective : To qualify the device being developed as per international standard ISO 5840 Cardiovascular implants – cardiac valve prosthesis – 2005 (Revised standard).	Approved
4.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Mr. Muraleedharan CV Received on 18.5.2007	“Development of improved tilting disc heart valve prosthesis”.  Species: Sheep Male  Number to be used : 20  Objective : To qualify the device being developed as per international standard ISO 5840 : Cardiovascular implants – cardiac valve prosthesis – 2005 (Revised standard).	Approved

5.	<p>Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. Prabha D. Nair 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: Sus. domesticus – 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, Thiruvananthapuram-695 012, Kerala /Dr. P.R. Umashankar 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>

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.  Species : Sheep – Weight 30 kg and above.  No. to be used : 10  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. Zydu Tower, Satellite Road, Ahmedabad-380 015. /Mr. V. D. Pawar, M. Pharm.	To evaluate the effect of ZY12 on cardiovascular system in telemetered dogs.  Species: Beagle Dogs – 6-24 months and 6-16 kg. weight  Number to be used : 8  Objective : Effect of NCEs on cardiovascular system will be evaluated in the telemetered conscious beagle dogs.	Approved

9.	National Brain Research Centre Naiwal Mode, Near NSG Campus Manesar – 122 050, Haryana. / Dr. Neeraj Jain Received on 08.06.2007	The effects of spinal cord and cortical lesions on the brain.  Species: Macaque  Number to be used: 48 (8 of these will be new born)  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 NH-8, Jaipur Highway Nainwal Mode, Manesar, Gurgaon (District), Haryana Dr Aditya Murthy Received on 08.06.2007	The role of basal ganglia and frontal cortex in control  (Approved by CPCSEA in XVIIth meeting held on 22.1.2007) and request for minor modification.  Species: Macaca sp.  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.

11.	National Brain Research Centre, Manesar (Gurgaon) Haryana – 122 050 / Mr. Narender K. Dhingra 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.  & Request for permission to use two monkeys of another approved protocol of Dr. Neeraj Jain  Species: Guinea pig – 450 – Adult ( 400-700 gms.)  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 Received on 18.6.2007	99/411: 28 Days Repeat Dose of Toxicity Study in Monkey by Oral Route  Species : (a) Rhesus Monkey (b) Adult 4.0 to 6 kg. (c) Male and Female (d) 14 Males and 14 Females (e) 45 Days for quarantine period and 30 days for study. The monkeys will be housed in restraintment 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.

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 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 have been approved by CPCSEA.</p>
14.	<p>Ranbaxy Laboratories Limited., R &amp; D-II, Sarhaul, Sector-18, Gurgaon-122 001/ Dr. N. Parthiban 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 No. to be used : (i) Dose range finding study of a new chemical entity (NCE-Ketolide class) in beagle dogs 9M+9F (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 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 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>

16.	<p>Ranbaxy Laboratories Limited., 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. 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., 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 No. to be used : 6 Dogs</p> <p>Objective : Bronchial asthma is a complex polygenic allergic disease involving a wide range of cell and mediator types (Barnes, 1998).</p>	Approved

18.	<p>Wockhardt Research Centre D-4, MIDC Area, Chikalhana, Aurangabad – 431 210 / Dr. M.B. Nandanwar</p> <p>Received on : 9.7.2007</p>	<p>Pharmacokinetics &amp; Toxicokinetic study of NCE's in Beagle Dog</p> <p>Species : Dog Strain : Beagle</p> <p>2-4 years</p> <p><u>No. to be used :</u></p> <p>(i) Pharmacokinetic Study : 8 Male &amp; 8 Female</p> <p>(ii) Toxicokinetic Study : 8 Male &amp; 8 Female</p> <p>Objective : To assess the Pharmacokinetics &amp; Toxicokinetics of NCE's for finalizing in vivo efficacy and long-term toxicity dose regimen</p>	<p>The Committee considered the proposal in depth but did not approve the proposal as the code of NCE's has not been provided.</p>
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<b>AGENDA ITEM NO.</b>	<b>SUBJECT IN BRIEF</b>	<b>DECISION OF CPCSEA TAKEN IN LAST MEETING</b>	<b>FOLLOW-UP ACTION</b>
<b>ITEM NO. 20.5</b>	<p>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.</p>	<p>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.</p>	<p>The Approval of the research proposal was conveyed to the Sree Chitra Tirunal Institute for Medical Science &amp; Technology, Thiruvananthapuram with a request that information regarding details of the breeding colony may be furnished.</p>
<b>ITEM NO. 20.6</b>	<p>Approval Of Animal House Facility by CPCSEA</p>	<p>(a) Indian Veterinary Research Institute, Mukteswar, Kumaon, Nanital - 263 138, Uttarakhand</p> <p>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.</p>	<p>The remarks of Committee were conveyed to the Director, IVRI, Muketeswar, Uttarakhand on 3.9.2007 with a request that the compliance report be submitted within stipulated period.</p>

		<p>(b) Central Avian Research Institute, Izatnagar-243 122, Bareilly, Uttar Pradesh</p> <p>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.</p> <p>(c) Bharat Serums &amp; Vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400 604, Maharashtra.</p> <p>The Animal House Facilities is approved for the purpose of Breeding and Experimentation of the animals namely: Horses and Ponies.</p>	<p>The remarks of Committee were conveyed to the Director, Central Avian Research Institute, Izatnagar-243 122 on 3.9.2007 with a request that the compliance report be submitted within stipulated period.</p> <p>The Approval of the Animal House Facility was conveyed to the Director, Bharat Serums &amp; Vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400 604, Maharashtra on 3.9.2007.</p>
<p><b>ITEM NO. 20.7</b></p>	<p>Any Other Item With The Permission Of Chairman</p>	<p>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.</p>	<p>The issue will be taken care at the time of preparation of SFC Note.</p>

**The Committee noted the status of the above proposals which were considered in the XXth meeting of CPCSEA.**

**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 – Reconsideration.**

The details furnished by the institute regarding establishment of the breeding colony were consider by the committee. The proposal is approved with the condition that only local breed non-show quality Basset Hound will be used.

**AGENDA ITEM NO.21.3 : REGISTRATION OF INSTITUTES WITH CPCSEA.**

The Committee noted that 1099 institutions have been registered with CPCSEA.

**AGENDA ITEM NO.21.4 : CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.**

**AGENDA ITEM NO.21.4.1: Update regarding proposals submitted earlier.**

S. No.	Name of the institute/Name of the Investigator	Project Title	Decision of XXI CPCSEA meeting
1.	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 6.9.2007	Development of de-cellularised animal tissue for cardio-vascular application. Species : Sheep – Weight 30 kg and above. No. to be used : 10  Objective : To evaluate processed bovine jugular vein for application as valved conduit between right ventricle and pulmonary artery.	<b>Approved.</b>
2.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala Received on 6.9.2007	Permission sought by Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BTM Wing), Poojapura, Thiruvananthapuram-695 012 to source locally available dogs for starting an in-house breeding colony to meet their requirements for experimental purposes	<b>Approved.</b>

3.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. D.S. Nagesh  Received on 13.3.2007	Ex-vivo evaluation of Centrifugal blood pump.  Species: Sheep  (Proposal on XVIII meeting held on 20.3.2007)	The Flow Chart has been furnished by the institute and the same has been found in order and the proposal is <b>Approved.</b>
4.	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. S.N. Rai  Received on 23.7.2007	Studies on Acacia nilotica pods replacing energy sources in ration of dairy cows on production performance and nutraceutical value of milk and milk products	<b>Approved.</b>
5.	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. K.K. Singhal  Received on 4.5.2007	Effect of feeding cottonseed produced from Bt cotton cultivar on feed intake, production and composition on milk in dairy cows	<b>Approved.</b>

**AGENDA ITEM NO.21.4.2: CONSIDERATION OF NEW PROPOSALS :**

S. No	Name of the institute/Name of the Investigator	Project Title	Decision of XXI CPCSEA meeting
1.	Tamil Nadu Veterinary and Animal Sciences University Madras Veterinary College, Chennai – 600 007./ Dr. A. Palanisamy.  Received on 7.8.2007	ICAR-NAIP Scheme on “Transcriptional level of developmentally important genes in buffalo preimplantation embryos”.  Species: Buffaloes  Number to be used: 15 female	<b>Approved</b>

2.	Tamil Nadu Veterinary and Animal Sciences University Madras Veterinary College, Chennai – 600 007./ Dr. C. Bandeswaran.,  Received on 7.8.2007	“Evolving appropriate time of feeding without altering the feed ingredients for enhancing rumen microbial biomass under existing cattle feeding practices”.  Species: Dairy cattle  Number to be used: 24 female	<b>Approved</b>
3.	Tamil Nadu Veterinary and Animal Sciences University Madras Veterinary College, Chennai – 600 007./ Dr. S. Gunasekaran,  Received on 7.8.2007	Evolving host specific probiotic and synchronizing it with Prebiotic for enhancing the performance of broiler chicken.  Species: Broiler chicks  Number to be used: 120	<b>Approved</b>
4.	Tamil Nadu Veterinary and Animal Sciences University Madras Veterinary College, Chennai – 600 007./ Dr. V. Selvakumar  Received on 7.8.2007	Developing Crude Palm oil based supplemental strategy to provide critical nutrients required for reproductive performance of cow.  Species: Cattle  Number to be used: 8 female	<b>Approved</b>
5.	Indian Veterinary Research Institute Izatnagar – 243 122 (U.P.), India / Dr. S.K. Agarwal  Received on 31.7.2007	Antiluteolytic Strategies – A Novel Approach to Enhance Fertility in Buffalo.  Species: Buffalo, rabbit, mice/rat  Number to be used: 20 buffaloes, 10 mice/ rats, 10 rabbits	<b>Approved</b>

6.	<p>Indian Veterinary Research Institute Izatnagar – 243 122 (U.P.), India / Dr. L.C. Chaudhary</p> <p>Received on 31.7.2007</p>	<p>Rumen microbial manipulations for mitigation of methane emission and productivity enhancement in dairy animals.</p> <p>Species: Buffalo</p> <p>Number to be used: (Year wise break-ups and total figures needed to be given)</p> <p>1<sup>st</sup> Year- 4 2<sup>nd</sup> Year- 3<sup>rd</sup> Year- 4<sup>th</sup> Year- 24</p>	<b>Approved</b>												
7.	<p>Indian Veterinary Research Institute Izatnagar – 243 122 (U.P.), India / Dr. O.K. Raina</p> <p>Received on 31.7.2007</p>	<p>Immunoprophylactic evaluation of potential vaccine candidates of Fasciola gigantica in domestic animals”.</p> <p>Species: Buffalo calves, rabbits and mice</p> <p>Number to be used:</p> <table border="1" data-bbox="651 1098 1078 1234"> <thead> <tr> <th>S.NO</th> <th>Species</th> <th>2008</th> <th>2009</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Buffalo calves</td> <td>40</td> <td>40</td> </tr> <tr> <td>2.</td> <td>Rabbit</td> <td>20</td> <td>10</td> </tr> </tbody> </table>	S.NO	Species	2008	2009	1.	Buffalo calves	40	40	2.	Rabbit	20	10	<b>Approved</b>
S.NO	Species	2008	2009												
1.	Buffalo calves	40	40												
2.	Rabbit	20	10												
8.	<p>Indian Veterinary Research Institute Izatnagar – 243 122 (U.P.), India / Dr. Dr. Umashanker</p> <p>Received on 31.7.2007</p>	<p>Effect of Aegle marmelos (Bel) and Ficus religiosa (Pipal) on reproductive performance in farm animals.</p> <p>Species: Mice, Rats, Goats, Cattle/ Buffalo</p> <p>Number to be used:</p> <p>II Year 20 goats III Year 20 cattle</p>	<b>Approved</b>												

9.	<p>Indian Veterinary Research Institute Izatnagar – 243 122 (U.P.), India /</p> <p>Dr. R. Somvanshi</p> <p>Received on 31.7.2007</p>	<p>Studies on etiopathology of enzootic bovine haematuria with special reference to bovine papilloma virus, fern and their interaction.</p> <p>Numbers to be used (Year-wise breakups and total figures needed to be given)</p> <p>Hill cattle and buffaloes 6-10 years, 100-250 kg, medium Preferably female Hill cattle 24 and buffalo 24</p> <p>Second year-Hill cattle 12 and Buffalo 12 Third year – Hill cattle 12 and Buffalo 12 18 months.</p>	<b>Approved</b>
10.	<p>Advinus Therapeutics Private Limited. Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-1/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F Main Study : 24M + 24F</p>	<b>Approved</b>

11.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-2/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>
12.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-3/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>

13.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-4/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>
14.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-5/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>

15.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-6/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>
16.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-7/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>

17.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. K. Venugopala Rao</p> <p>Received on : 6.8.2007</p>	<p>Evaluation of test item – for Subchronic toxicity in Beagle dogs</p> <p><b>Project Code : SCD-8/07</b></p> <p>Species : Beagle dog</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD, OPPTS, US, FDA, ICH, EMEA, Schedule Y, Drugs and Cosmetics Act, ( 2<sup>nd</sup> Amendment) 2005, Government of India of India, Gaitonde Sub committee guideline No. 6.2.0., B.i., Government of India). The number of animals required for each study is</p> <p>Preliminary Study : 5-7M+5-7 F</p> <p>Main Study : 24M + 24F</p>	<b>Approved</b>
18.	<p>Advinus Therapeutics Private Limited.</p> <p>Plot Nos. 21&amp;22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. S.M. Sulaiman</p> <p>Received on : 6.8.2007</p>	<p>Subchronic (90 day) feeding study in Goats</p> <p><b>Project Code : SCG-1/07</b></p> <p>Species : Goats</p> <p>Number to be used : As per the regulatory /guideline requirements (OECD and DBT, Government of India). The number of animals required for the study is 60 (30 M + 30 F)</p>	The Committee considered the proposal in depth but did <b>not approve</b> the proposal as the justification of animals to be used have not been mentioned in the proposal. Experimental design is also to be furnished.
19.	<p>Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow – 226 001/Dr. Sharad Sharma</p>	<p>Herbal Medicament : 28 Days Repeat Dose of Toxicity Study in Monkey by Oral Route</p> <p>Species : Rhesus Monkey</p> <p>Number to be used : 14 Males and 14 Females = Total 28</p>	<b>Approved</b> with a condition that the Animal house Facilities of the Institute should already have been approved and renewed by the CPCSEA.
20.	<p>Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow – 226 001/Dr. Amit Mishra</p>	<p>90 days Inhalation Safety Study of Microparticle DPI containing 1::1:2 isoniazid, rifabutin, poly lactide in Rhesus Monkeys</p> <p>Species : Rhesus Monkey</p> <p>Number to be used : 24</p>	<b>Approved</b> with a condition that the Animal house Facilities of the Institute should already have been approved and renewed by the CPCSEA.

21.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. Niranjana D. Khambete Received on 5.9.2007	Implanted Neural Interfaces and Control Schemes for Artificial Hand Control Species : Goat Number to be used : 5 (Five)	<b>Approved</b>								
22.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. Chandra P. Sharma Received on 5.9.2007	Oral Delivery of Insulin Species : Large white Yorkshire (pig) Number to be used : Year wise break up (January 2008 to July, 2009) <table border="1"> <thead> <tr> <th>First</th> <th>Second</th> <th>Third</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>21</td> <td>21</td> <td>21</td> <td>63</td> </tr> </tbody> </table>	First	Second	Third	Total	21	21	21	63	<b>Approved</b>
First	Second	Third	Total								
21	21	21	63								
23.	Jai Research Foundation (JRF) Valvada – 396 108 Dist. Valsad, Gujarat./Dr. Virendrashinh Received on 7.9.2007	Repeated Dose (180 Day) Toxicity Study on NCR 019 in Dogs. Species : Beagle Dog Numbers to be used & Sex : 24 M + 24 F	<b>Approved</b>								
24.	Jai Research Foundation (JRF) Valvada – 396 108 Dist. Valsad, Gujarat./Dr. Virendrashinh Received on 7.9.2007	Repeated Dose (28 Day) Toxicity Study on NCR 019 in Dogs. Species : Beagle Dog Numbers to be used & Sex : 12 M + 12 F	<b>Approved</b>								

**AGENDA ITEM NO. 21.5: APPROVAL OF ANIMAL HOUSE FACILITY BY CPCSEA**

**(a) Jai Research Foundation, Vapi, Gujarat**

The Animal House Facility has been approved by the Committee for the purpose of **Breeding and Experimentation** of the animals namely: Beagle Dog.

**AGENDA ITEM NO. 21.6: ANY OTHER ITEM WITH PERMISSION OF CHAIRMAN**

**(a)** The issue regarding appointment of Expert Consultant in CPCSEA in the regular pay scale and strength of the Ministry as raised by the members in earlier meeting (XXth) is to be expedited

(b) Dr. Vasantha Muthuswamy, a member of the Committee circulated a book entitled **“Guidance Document on Humane Care and Use of Laboratory Animals”** published by **ICMR**, New Delhi, for information of the members of the Committee. The Chairman, CPCSEA along with all the members of the Committee conveyed their sincere thanks to Dr. Muthuswamy.

The meeting ended with a vote of thanks to Chair.

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**The following Members were present for the meeting on 18.9.2007**

1. Shri. B.S. Parsheera, Chairman  
Additional Secretary,  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.
2. Shri. G. Balachandhran Vice Chairman  
Joint Secretary (Animal Welfare),  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.
3. 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.
4. 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.
5. 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.
6. Dr. Shashi Motilal,  
Professor (Philosophy),  
University of Delhi,  
7, Vaishali Apartments, IIT/Delhi, Hauz Khas,  
New Delhi-110 016.
7. Dr. D. Swaroop  
Head, Division of Medicine,  
IVRI, Izatnagar – 243122  
Uttar Pradesh
8. Dr. Kondavalla Venkaiah,  
Head & Addl. Director,  
Bio-Statistics Department,  
National Institute of Nutrition,  
Hyderabad-500 007.

9. Dr. K. Nachimuthu,  
Director of Research,  
Tamilnadu Veterinary and Animal Sciences University (TANUVAS),  
No.4, Dhamodara Street, Panchvadi, Chetpet,  
Chennai-600 031.
10. Prof. A. J. Rao ( Retd),  
Department of Biochemistry,  
Indian Institute of Science,  
Bangalore – 560012.

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

1. Prof. Anup Kumar Nayak,  
Wildlife Institute of India,  
Post Bag #18, Chandrabani,  
Dehradun – 248 001, Uttaranchal.
2. Dr. P. Balakrishnamurthy,  
Director,  
International Institute of Biotechnology & toxicology (IIBAT),  
12, Harleys Road, Kilpauk,  
Chennai - 600 010.
3. Dr. T.P.R. Bhardwaj,  
Senior Consultant, Haematologist,  
Apollo Hospitals, 21, Greams Lane,  
Off. Greams Road, Chennai-600 006.

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