MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 SPRING MEETING 2010
MARCH 25TH AND 26TH, 2010

THURSDAY MARCH 25TH, 2010

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its semi-annual meeting of the technical committee and administrative advisors on March 25th and 26th at the FDA Center for Veterinary Medicine (CVM), 7519 Standish Place, Rockville, MD

ATTENDANCE AM MEETING

NAME	AFFILIATION	EMAIL ADDRESS
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The NRSP-7 technical committee is made up of a National Coordinator, four Regional Coordinators, four regional Administrative Advisors, and liaisons from USDA and FDA. The National Coordinator is Dr. John Babish (Cornell University). The Regional Coordinators are Dr. Lisa Tell (University of California, Davis), Dr. Thomas Vickroy (University of Florida), Dr. Ronald Griffith (Iowa State University), and Dr. Paul Bowser (Cornell University). The Administrative Advisors in attendance are Dr. Margaret Smith (Cornell University) and Dr. John Baker (Michigan State University AES), Chairman of Administrative Advisors. The USDA representative is Dr. Gary Sherman (Washington, DC) and the FDA liaison is Dr. Meg Oeller (Rockville, MD).

9:00 – 12:00 INTRODUCTIONS
Introductions and meeting organization

Dr. John G. Babish started the meeting with a round of introductions followed by a description of the program's ongoing efforts to increase funding and dealing with increasing research costs, and more rigorous regulatory requirements that have evolved over the program's twenty-five year existence.

He described the mission of the program as fourfold: *Identify* animal drug needs for minor species and minor uses in major species, *Generate* and *disseminate* data for safe and effective therapeutic applications, and *Facilitate* FDA/CVM approvals for drugs identified as a priority for a minor species or minor use.

To accomplish these goals, the Minor Use Animal Drug Program functions through the coordination of efforts among animal producers, pharmaceutical manufacturers, FDA/CVM, USDA/Cooperative State Research, Education, and Extension Service, universities, State Agricultural Experiment Stations and veterinary medical colleges throughout the country.

Dr. Babish then outlined the format of the meeting as an interaction between CVM reviewers and Regional Coordinators to discuss both general issues as Good Laboratory Practice inspections and specific concerns in recent protocol or research submissions.

Welcome from Dr. Bernadette Dunham

Dr. Dunham, the Director of the FDA Center for Veterinary Medicine (CVM), welcomed everyone and began the discussion with her vision of changes within CVM and the future of the MUMS and MUADP. In her remarks, she again stressed the need for collaboration with stakeholders and the need to demonstrate to the leaders at USDA and in the Congress the impact of the program on both animal health and public health.

Dr. Dunham announced the appointment of Michael R. Taylor as deputy commissioner for foods at the Food and Drug Administration (FDA) in January 2010. He is the first individual to hold the position, which was created along with a new Office of Foods in August 2009. Mr. Taylor is leading FDA efforts to

- Develop and carry out a prevention-based strategy for food safety
- Plan for new food safety legislation and
- Ensure that food labels contain clear and accurate information on nutrition

Dr. Dunham praised the program members for their efforts to ensure funding through continued lobbying and provided guidance into the most effective ways of establishing strong connections with stakeholders and legislators. She provided insight into the budget process both from the standpoint of the agencies of the executive branch and from the congressional side. Changes in the scope of the program and in the funding mechanisms need to be planned well in advance and must be supported by clear objectives and accomplishments. The MUADP/NRSP-7 program has a good story to tell. Dr. Dunham encouraged the members of the program and their stakeholders to take this important message to the USDA and the congress to encourage their support.

She recounted changes at FDA that mirror the need to focus on “One Health” initiatives that link animal and human health concerns. The One Health concept is a worldwide strategy for expanding interdisciplinary collaborations and communications in all aspects of health care for humans and animals. The synergism achieved will advance health care for the 21st century and beyond by accelerating biomedical research discoveries, enhancing public health efficacy, expeditiously expanding the scientific knowledge base, and improving medical education and clinical care. When properly implemented, it will help protect and save untold millions of lives in our present and future generations.

Finally, Dr. Dunham discussed her plans to make the FDA/CVM web site (http://www.fda.gov/AnimalVeterinary/default.htm) easier to navigate. Among the issues generally cited by visitors to the site, was the desire to follow drugs through the approval process

more accurately. This was contrasted to the ability to follow patent applications through the patent approval process at the US Patent and Trademarks site (http://www.uspto.gov/).

REPORTS FROM THE REGIONS

Western – Dr. Lisa Tell

Progress of Work and Principal Accomplishments:

Active Regional Projects:

ADR#325 – Florfenicol (Nuflor® Injectable Solution) for sheep for respiratory disease
The human food safety and efficacy studies required by FDA/CVM for the old formulation of florfenicol (Nuflor Injectable Solution) have been completed. All of the data from this project have been published. This project has been terminated and this termination has been entered into RUSTI. The data from the HFS study has been organized and a technical report written. The final technical report for the human food safety study is undergoing quality assurance review and is projected to be complete by March 31, 2010. Once the QA review is completed, a "road map" for CVM will be created and the technical report submitted.

ADR#350 – Florfenicol (Nuflor Gold®) for sheep for respiratory disease
A pilot study evaluating administration route (IM vs. SC) and doses of 20 (IM) or 40 (SC) mg/kg was performed in September and October of 2009. All of the samples (n=672; 28 samples for 24 animals) have been analyzed. A product development meeting was held on November 18th , 2009 with CVM, the sponsor and the Minor Use Animal Drug Program. Another dose range finding study using the SC route of administration is to be performed. Once the proposed label dose is determined, the Target Animal Safety Study will be performed. Since the last meeting a subset of samples have been analyzed evaluating differences between serum and plasma samples.

ADR#299 - Pirlimycin for Dairy Goats
Project on hold until funding is identified and CIDR goat studies are completed.

ADR#295 - Strontium Chloride for Salmonids. Steve Schroeder
There is nothing to report. Status of the project needs to be changed.

ADR#338 – Spectramast™ LC Sterile Suspension for Mastitis in Dairy Goats
Project on hold until funding is identified and CIDR goat studies are completed.

ADR#135 – Erythromycin in Salmonids
The environmental assessment was sent to FDA/CVM for review and they requested a revision of certain sections and that a chronic toxicity study with *Daphnia magna* be performed. This chronic toxicity study has been performed and will address CVM concerns regarding chronic toxicity to aquatic insects. In addition, a study describing the physiochemical properties of erythromycin has been performed. Because of the physical characteristics of ERTT, an empirical pKa could not be established. A draft of the revised environmental assessment report for erythromycin in salmonids is presently in preparation and has a targeted date for completion on December 7th, 2009. The report for the range-finding chronic toxicity study for the *Daphnia magna* has been reviewed and will be submitted to CVM. The EA was sent to Eric Silberhorn on January 20, 2010 for preliminary review. Christine Moffitt is working on the White Paper for submission.

ADR# 311 –Lincomycin soluble powder for foulbrood disease in Honeybees
The human food safety technical section is complete. The effectiveness technical section is pending.

Collaborative Projects:

ADR# 258 - CIDRg (Controlled Internal Drug Release Devices) in Sheep
FDA/CVM has accepted all of the data for this study and the information has been summarized by FDA/CVM in a Public Master File. Completed sections are effectiveness, target animal safety, human food safety, and environmental safety. This project was announced in the Federal Register, Vol 74(220), pg 59073, November 17, 2009.

ADR#272 - Romet for Game birds
No Western region activity on this project. Need to check what region this project was originally assigned to.

ADR#280 - Fenbendazole in Game Birds (Pheasants, bobwhite quail, partridge)
A conference call with Merck/Intervet/SP was held on Thursday, February 25th. See Southern Region Report.

ADR#324 - Progesterone CIDRs for Goats (TAS, Milk Residue Study, and Efficacy)
The target animal safety study technical report has been accepted by FDA/CVM (February 2008). The milk residue study has been completed and the quality assurance inspection has been completed. The final technical report was sent to FDA/CVM in December 2008 and accepted October 2009. FDA/CVM has provided comments regarding the efficacy protocol. The protocol has been accepted for concurrence. The efficacy study was started at UC Davis and Iowa State University during the fall of 2009. A quality assurance inspection was performed for the stability of progesterone in goat tissue during frozen storage in September 2009. A quality assurance inspection was performed in October 2009 for CIDR-G insertion and removal.

ADR#340 - Tulathromycin in Goats (Collaborative project with the North Central region)
The quality assurance was performed for the target animal safety study in February and March 2008. A tissue liquid chromatography/mass spectrometry method for analysis of the samples has been validated using 664 spiked samples to validate 4 tissues. Validation of analytical methods for liver, muscle, kidney and fat samples is complete. Plasma (444) and tissue (180) samples from the target animal safety have been analyzed. The quality assurance for the target animal safety report was completed November 2009. Plasma samples from the Human Food Safety Study have been analyzed and the PK data has been generated. Tissue samples from the Human Food Safety Study are currently being analyzed from 30 animals. To date, muscle, liver, kidney, and injection site samples have been analyzed from all 30 animals.

Other Projects/Activities:

Excede (Ceftiofur Crystalline Free Acid) in Goats: Study has been completed in non-lactating and lactating goats. The serum and milk samples have been analyzed and the pharmacokinetic data modeled. The manuscript has been written and submitted to the Journal of Veterinary Pharmacology and Therapeutics for publication.

New Projects:

Ceftiofur for Treating *Arcanobacterium pyogenes* Respiratory Infections in Deer: 27 isolates from deer have been collected. Due to the sensitivities, and pathology associated with this organism, this project is not currently being pursued for a label claim for either tulathromycin or ceftiofur.

CIDRs for Deer: Conference call with Albert Ramudo. Dr. Ramudo will check into the interest on Pfizer's part for such a study.

Laboratory Report:

Most of the activity continues as sample analysis in the laboratory. Results and plans are reported under separate projects above.

Usefulness of the Findings:

The findings from all of the studies above will be utilized to fulfill the data requirements for the FDA/CVM approval of these drugs for use in minor species.

Work Planned for Remainder of the Year:

Over the next year our primary goals are to continue the CIDR-G Efficacy study, finish the analyses for the goat tulathromycin project, and finish the salmonid erythromycin environmental assessment. If the fenbendazole in game bird study starts again, we will be prepared to do the sample analysis.

Manuscripts Submitted, Accepted or Published Since the Last Meeting:

Rowe, J, Tell, L, Griffith, R, Lee, K, Hallford, D. Progesterone Milk Residues in Goats Treated with CIDR-G® Inserts. In Press: Journal of Veterinary Pharmacology and Therapeutics.

Dore, E, Angelos, J, Rowe, J, Wetzlich, S, and Tell, L. Pharmacokinetics of ceftiofur crystalline free acid and metabolites after single subcutaneous administration in lactating and non-lactating domestic goats (*Capra aegagrus hircus*). In Press: Journal of Veterinary Pharmacology and Therapeutics.

Critical Review:

1. *Work accomplished under the original project*

The original objectives of the project were to conduct a national program to obtain minor and specialty animal drug clearances (tolerances, exemptions and registrations) in cooperation with state, federal and industry personnel to include:

a. Determination and prioritization of minor-use needs and data requirements.
b. Review, analysis and evaluation of minor-use research proposals.
c. Development and assembly of data for minor-use registrations.
d. Preparation and submission of petitions for drug registrations.

Considering these objectives, considerable progress has been made towards achieving them for each of the active projects listed above, particularly in the development of the data (the actual research), its analysis, assembly and interpretation, and submission to the FDA/CVM for review.

2. *The degree to which objectives have been met*

The degree to which these objectives have been met varies from project to project, however, in most all cases there has been progress. Those projects on which there has been no movement are reevaluated during each meeting of the NRSP-7 Technical Committee and decisions made on whether to continue to pursue them or move them into the inactive project list.

3. *Incomplete work or areas needing further investigation*
All of the projects listed above have some work that needs to be completed before they are approved by the FDA/CVM. In some cases this is just the FDA/CVM review, while in others there is work needed by the NRSP-7 project. The NRSP-7 work that is undertaken each year within the Western Region is based on the availability of qualified and interested investigators, the capacity of the regional laboratory to validate methods and analyze samples, and cooperation of the pharmaceutical manufacturers whose products are investigated.

Northeast Region: Dr. Paul Bowser
Progress of the work and principal accomplishments
The Northeast Region NRSP7 has been without funding from the period of 09/2008 to 09/2009. Due to this financial situation, work accomplished during this period was limited primarily to providing administrative support to the New York State Department of Environmental Conservation in their conduct of field trials under our INAD 10-320 for the use of Oxytetracycline in fish.

Species Grouping Project:
INAD 10-320 Oxytetracycline in Fish
INAD 10-823 Romet-30 in Fish
INAD 11-145 Florfenicol in Fish
No additional work has been performed on this project during this study period.

Usefulness of the findings:
In all cases, the findings to date over the course of these projects serve as the foundation for continued work on these compounds. The Human Food Safety Studies completed to date in fish are consistent with what was expected; namely that the elimination of therapeutic compounds from the edible portion of the fish tested are within the withdrawal times currently specified for labels, or available in the literature for oxytetracycline, Romet-30 and Aquaflor (Florfenicol) in trout, salmon and catfish.

Work planned for next year:
Species Grouping Project:
INAD 10-320 Oxytetracycline in Fish
INAD 10-823 Romet-30 in Fish
INAD 11-145 Aquaflor (Florfenicol) in Fish

Future work is being hampered by a lack of funds in the Northeast Region. We anticipate our efforts on this project to center around the continued provision of administrative support of Efficacy Studies of oxytetracycline in a collaborative effort with the New York State Department of Environmental Conservation. The particular focus of the efficacy trials will be for the treatment of bacterial diseases not currently on the label for treatment of bacterial diseases of cool water species such as walleyes, muskellunge and tiger muskellunge (hybrid muskellunge X northern pike). These studies will be initiated when diagnosed field cases can be identified that will lend themselves to the implementation of controlled field studies.

Other:
We are also considering the development of a project that centers on the question of Iodophore disinfection of fish eggs to prevent the vertical transmission of Viral Hemorrhagic Septicemia Virus. Contact has been made with a potential sponsor,

Western Chemical, which expressed interest in developing collaboration with the MUADP.

CRITICAL REVIEW (Northeast Region)

1) Work accomplished under the original project:

The original objectives of the project were to conduct a national program to obtain minor and specialty animal-drug clearances (tolerances, exemptions and registrations) in cooperation with state, federal and industry personnel. The mission of NRSP-7 is:

To identify animal drug needs for minor species and minor uses in major species,
To generate and disseminate data for safe and effective therapeutic applications, and
To facilitate FDA/CVM approvals for drugs identified as a priority for a minor species or minor use.

Under the framework of this mission, progress has been made in the following areas:

(A) Use of hydrogen peroxide for the control of bacterial gill disease in fish.
(B) Species Grouping in Fish, using the compounds Oxytetracycline, Romet-30/Romet-TC and Aquaflor as test articles.

2) The degree to which the objectives have been met:

Work has focused on a number of important therapeutic compounds in aquatic animals. The work is being conducted in a deliberate manner with the goal of developing appropriate data that will be submitted in support of a label for these compounds. An initial step in this process is the publication of the data in the peer reviewed scientific literature. While we consider it extremely important to have such peer-reviewed information available for the veterinary community, should they consider an extra-label use, the ultimate goal is to secure a label for the product. As an additional goal, the work is being done in a manner that could justify a species-grouping concept for finfish cultured in the United States. Additional work is currently being impacted by a lack of funds in the Northeast Region.

Incomplete work or areas needing further investigation:

The development of a crop- (species-) grouping concept is seen as imperative for supporting efforts to gain labels for therapeutic compounds for fish. Our work on Oxytetracycline, Romet-30/Romet-TC and Aquaflor (Florfenicol) in fish is proposed to be part of an effort to utilize those compounds as models in this effort. We expect that our efforts in developing a species-grouping concept for fish will be a major undertaking in the upcoming years.

Principal Publications (during the past year):

Publications:

Bowser PR, Kosoff RE, Chen C-Y, Wooster GA, Getchell RG, Craig JL, Lim P, Wetzlich SE, Craigmill AL, Tell LA. Florfenicol residues in Nile tilapia after 10-d oral dosing in feed: Effect of fish size. J Aquat Anim Health, 21: 14-17, 2009.

Kosoff RE, Chen C-Y, Wooster GA, Getchell RG, Bowser PR, Clifford A, Craig JL, Lim P, Wetzlich SE, Craigmill AL, Tell LA. Florfenicol residues in three species of fish after 10-day oral dosing in feed. J Aquat Anim Health, 21: 8-13, 2009.
7.

North Central – Dr. Ronald W. Griffith

Goat CIDR-G Milk Residue

Study report accepted. We received word from Dorothy Bailey that our requested zero-day withholding time for milk has been approved. This will allow us to complete the efficacy study for milk goats.

Goat CIDR-G Tissue Residue

Sixteen meat-type does were purchased and CIDRs placed in 8 does on October 24, 2009. The CIDRs were removed on November 11 and muscle and fat tissues harvested according to protocol (just less than 12 hr. following CIDR removal). The reproductive tracts were removed and examined by a board certified theriogenologist. The tissue analytical work was performed within two weeks by Dr. Dennis Hallford at NMSU. P4 in goat muscle and fat tissues is stable to multiple freeze-thaw cycles as expected. The tissue levels of progesterone 12 hr. following removal of the CIDRs were significantly below progesterone levels in tissues of does with intact corpora lutea that did not receive the CIDRs. The study report is being prepared.

Goat CIDR-G Effectiveness

The NC and Western Regions are cooperating on this study. The Western Region conducted a study in dairy goats with the U.C. Davis herd. The NC region (Iowa State) used a herd of 54 meat-type does for their study. In Iowa, the CIDRs were placed on October 9, 2009 and were removed on October 27, 2009. Estrus synchronization occurred in 90 plus percent of the does and pregnancy rates were very good on ultrasound. The owners will be following this group through to kidding as part of reproductive safety.

Contacts have been made for placing CIDRs in at least three dairy goat herds in Wisconsin and hopefully an equal number in North Carolina during the fall 2010 breeding season. We also have investigators willing to cooperate in Tennessee and Texas. We have one other group of meat goats lined up for next fall in Iowa and need to find at least one more herd. Our targets are 6 herds of approximately 60 does each in at least two different geographic areas of the U.S. We need to do 6 herds for dairy goats and 6 herds for meat goats. Our target for submission of the completed study report is spring or summer 2011.

Lasalocid in Pheasants Efficacy

The study was completed in 2007 and the study report QA'd by Sandy Ogletree several months ago. The study director has recently responded to a request to submit the study report and it will hopefully be submitted soon.

Lasalocid in Pheasants TAS

The study was completed the first week of August, 2009. The study report has been written except for the section dealing with the statistical analysis. The student involved promised to work on this over the Christmas break and Spring break but did not. There were no adverse effects noted when lasalocid was fed at 1X, 2X and 3X the highest recommended dose for chickens and turkeys. These levels of lasalocid were fed for 6 weeks.

Bioclip in Sheep

No report. Too many projects at the moment to devote any time to this.

Draxxin (tulathromycin**) Target Animal Safety in Goats**
The study report has been submitted to the FDA/CVM. We hopefully will hear back in July or August, 2010. Dr. Kris Clothier has a manuscript accepted by the Journal of Pharmacology and Therapeutics.

Draxxin (tulathromycin**) Tissue Residue**
Thirty-three male/castrated male goats were obtained from local producers in July 2009. We experienced some death loss and had to initiate treatment for coccidiosis in a few of the dairy breed goats and for *Haemonchus contortus* in a few of the meat breed goats. As a result, we needed to conduct and justify an extended "washout" period and replace 4 of 5 goats that died. Tissues were collected at 1, 5, 11, 18, 25 and 48 days post treatment. The methods for tissue extraction and tulathromycin analysis have been validated and the tissues were shipped to the analytical lab at U.C. Davis. Processing and analysis of the tissues is underway.

Draxxin (tulathromycin**) Efficacy in Goats**
A protocol based upon determination of AUC/MIC was prepared and submitted. It was decided that we needed some preliminary pharmacokinetic and MIC data in order to set a realistic target. We have procured sufficient isolates of *Mannheimia haemolytica* (over 30) but only about 14 isolates of *Pasteurella multocida.* MIC's have been determined on all of these. We have performed a larger pharmacokinetic study (using the 25- and 48-day goats of the HFS study above). Plasma samples were collected from these 10 goats with much earlier and more frequent sampling times. The analytical lab at U.C. Davis has completed analysis of the plasma samples. This study is the subject of a requested pre-submission conference.

Southern – Dr. Thomas Vickroy
Projects in Progress

RABBITS
ADR – 0107 Ivermectin & Rabbits
The human safety and target animal safety reports are being prepared subject to completion of freezer stability. This task was treated as secondary to the fenbendazole in game birds but is now being pushed to completion.

BIRDS
ADR - 0280 Fenbendazole & Game birds
The human safety report was submitted to FDA-CVM. The concerns of UC-Davis QA resulted in (a) withdrawal of quail part of the report [QA problem with Webb's dual role as study director and QA inspector plus very problematic withdrawal conclusions]; (b) letters from site personnel were submitted to try and mitigate lack of in vivo QA inspection; (c) in vitro section QA was certified by UCD. We have just heard that the pheasant study has been rejected but we have no information of why or whether there is any possibility of re-submission. The TAS report is now complete but lacks investigator's final input and QA we are planning a 60-day completion. We are very concerned with the GLP QA aspect as it has some of the same problems as the rejected HFS submission.

SMALL RUMINANTS
ADR – 0210 Fenbendazole & Red Deer & ADR – 0216 Fenbendazole & Fallow Deer.
Intervet / Schering Plough/Pfizer are still working on their combined project pipeline priorities so this project is on hold. Dose seems a critical point to be solved.

ADR - 0294 Lasalocid and Deer / ADR - 0298 Lasalocid and Goats
Problem is that Alpharma will only proceed if there is a zero withdrawal time. We have had problems with the assay and hope to gain guidance from CVM at this meeting. The problem is the established method is non-reproducible so validating/bridging of the assay is problematic. Alpharma seem reluctant to file for designation that would eliminate applying for the FDA competitive funds to work on an acceptable assay. Also we have not submitted a protocol for the HFS study in either goats or deer. See below for Texas A&M University collaboration.

We have exchanged drafts of the HFS protocol for lasalocid in goats with Dr Fajt [Texas A&M University]. It has not been readied for submission to FDA. Texas A&M University is developing a drug development program and will probably have it's own QA unit.

BEES
ADR – 0343 Remebee and Honey bees
The Remebee project is with Beeologics for an Israel Acute Paralysis Virus [IAPV] specific double strand RNA product for prevention of collapsing colony disorder. The company has obtained an INAD and following a teleconference with FDA/CVM last month, has gained both EA exclusion and approval for consumption of honey from treated hives (treatment has to end before honey flow). NRSP-7's role is of a possible advisor until FDA considers all the data submitted to determine what gaps there are and how large.

Work Planned for the remainder of the Year:

- Maintain lab and staff at GLP level.
- Continue efforts for collaborative studies for gaining approval of fenbendazole & lasalocid in deer, and lasalocid in goats.
- Prepare, in coordination with the National Coordinator, INAD submissions for studies conducted under the aegis of the Southern Region. Initial preparation of written responses to CVM review of all of the data submitted for each project. This is often a time consuming and unrecognized activity associated with the completion of each project and may require considerable correspondence and conversation.
- Continued collaborative work with the other regions is anticipated and may include unplanned studies to address critical needs and opportunities to collect data.
- Continue the development of the MUADP/NRSP-7 web site with possible re-implementation of the RUSTi database.

New / Proposed Projects:
Currently, the primary effort is to complete existing studies and we are trying to collaborate with Texas A&M University to start work on lasalocid deer and goat projects.

Web Site
The NRSP-7.org web has continued to function well but is need of some development such as PowerPoint Presentations. The University is increasing security and is centralizing control of IT. We are concerned but we have been model citizens plus we actually got our original permission to host the web site without obvious use of the ufl.edu domain from the current head of IT. The MUMSRx web database continues to be updated – it alone receives 1-2 hits each day. RUSTi is alive but with loss of biological scientist we have kept a low profile. Further development will have to wait upon program's choice of a successor for the current coordinator. However we would like

some discussion and guidance on off-site housing of the web site and records of minutes, reports, and current as well as past project documents.

REPORTS FROM LIAISONS

NIFA/USDA – Dr. Gary Sherman
Dr. Gary Sherman continued his discussion from fall 2009 on the funding methods of the program and the complexities of the budget process. As personnel changes continue to occur at the agency, he also described the latest organizational changes at NIFA/USDA. This includes the recent changes at the USDA Cooperative State Research, Education, and Extension Service (CSREES).

Next in his presentation, Dr. Sherman emphasized the need for MUADP/NRSP-7 to recognize the new Research, Education, and Economics (REE) priorities of NIFA and to stress the role of MUADP in specific priority areas. He reiterated the REE priorities as

- Global Food Security and Hunger
- Climate Change
- Sustainable Energy
- Childhood Obesity
- Food Safety

During the presentation, it was discussed how MUADP/NRSP-7 can be of great value in the areas of food security and food safety.

As in the 2009 fall meeting, a good deal of discussion centered on the goal of changing NRSP-7 from a congressionally directed line item to a program with its own authority. NRSPs are a type of program funded through the Agricultural Experiment Stations of State Universities using Hatch funds. With its own authority, the “Minor Use Animal Drug Program” would be funded through a special grant. The hope is that funding would be more reliable and based on goals and needs that differ from the other NRSPs. The name Minor Use Animal Drug Program is the one currently used in the federal budget to describe NRSP-7, and the committee has decided to use that name.

A vote taken by the Technical Committee following this discussion of the MUADP funding category was unanimous to have Dr. Sherman work in concert with the Technical Committee to move the program’s current status from noncompetitive to competitive within NIFA/USDA. It was felt that this move would be necessary to support increased funding and maintain viability in the current political climate that discourages Congressional “earmarks”.

Report from CVM – Dr. Meg Oeller
Dr. Oeller began her presentation with a short review of the active projects in each of the regions and discussed any issues regarding these projects with the respective Regional Coordinator. In summary those active projects discussed included:

ADR	DRUG	FORMULATION	SPECIES	INDICATION	FIRM	REGION	INAD
135	Erythromycin	Premix	Salmonids	Bacterial kidney disease	Bimeda	W	6013
325	Florfenicol	Injectable	Sheep	Respiratory infections	Schering	W	10-958
311	Lincomycin	Powder	Honey bees	American Foulbrood	Pfizer	W	10-776
299	Pirlimycin	Intramammary	Goats	Mastitis	Pfizer	W	Pending
295	Strontium Chloride	Immersion	Fish	Otolith marking	Western Chemical	W	10-536
216	Fenbendazole	Premix	Deer	Gastrointestinal parasites	Intervet	S	10-993
280	Fenbendazole	Premix	Pheasants & partridges	Gapeworm & capillaria	Intervet	S	10-062
107	Ivermectin	Injectable	Rabbits	Ear mites	Merial	S	9557
294	Lasalocid	Premix	Deer	Coccidiosis	Alpharma	S	10-746
298	Lasalocid	Premix	Goats	Coccidiosis	Alpharma	S	10-872
343	Remebee™	Oral liquid	Honey Bees	Israeli Acute Paralysis Virus	Beeologics	S	MUMS
334	Florfenicol	Oral	Fish (Finfish)	Bacterial infection	Schering	NE	11-145
285	Oxytetracycline	Feed	Fish(Various)	Vibriosis	Phibro	NE	10-320
313	Sulfadimethoxine & ormetoprim	Premix	Fish	Bacterial infections	Alpharma	NE	10-823
272	Sulfadimethoxine & ormetoprim	Premix	Pheasants	Bacterial infections	Alpharma	NE	10-804
324	Progesterone	CIDR	Goats	Estrus Synchronization	Pfizer	NC/W	11-389
235	Lasalocid	Premix	Pheasants	Coccidiosis	Alpharma	NC	9096
340	Tulathromycin	Injectable	Goats	Respiratory infection	Pfizer	NC	11-512
339	Tulathromycin	Injectable	Sheep	Respiratory Infection	Pfizer	NC	11-513

Following the review of regional projects, Dr. Oeller provided an update on INADs to be terminated. A list of ADUFA (Animal Drug User Fee Act of 2003) waiver requests was given to the attendees. The INADs were divided into three categories: (1) INADs behind approvals were archived, (2) INADs for active projects were maintained, and (3) INADs for abandoned projects were terminated.

Dr. Oeller placed into discussion two potential project questions – banamine (flunixin meglumine) for sheep and goats, and a request from the American Sheep Industry Association's Paul Rodgers for a new sheep dip dewormer Zolvix.

Website issues discussed included (1) the need to update the FAQ section, (2) inclusion of a project list with status updates, (3) should RUSTI be public, and (4) an update of links to FDA/CVM, stakeholder associations and NIFA/USDA.

Finally, Dr. Oeller led a discussion on the usefulness of a protocol archive on RUSTI and encouraging designation status by sponsors. Both ideas were strongly supported by attendees. She concluded her presentation with the introduction of the likelihood of a new FDA/CVM liaison replacing her due to the dramatic increase in her responsibilities at OMUMS. The timeline for this change has not been developed, but is coming.

12:00 – 1:00 Lunch

Discussion of protocols and submission requirements with reviewers from CVM

The Regional Coordinators presented quick overviews of their on-going projects and then joined the CVM reviewers in a very helpful discussion of currently available guidance documents, the format of submissions for review, protocol development, and various problems with the use and validation of regulatory methods. The committee truly appreciates the time and assistance provided by the reviewers.

FRIDAY NOVEMBER 20TH, 2009 EXECUTIVE WORKING SESSION

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its second day of the spring semi-annual meeting of the technical committee and administrative advisors at the FDA Center for Veterinary Medicine (CVM), 7519 Standish Place, Rockville, MD.

MEETING ATTENDEES

NAME	AFFILIATION	EMAIL ADDRESS
Dorothy Bailey	FDA/CVM	dorothy.bailey@fda.hhs.gov.
Gary Sherman	USDA/CSRESS	gsherman@nifa.usda.gov
John Babish	NRSP-7	jgb7@cornell.edu
John C. Baker	AA/MI AES	Baker@anr.msu.edu
Lisa Tell	NRSP-7/UC Davis	latell@ucdavis.edu
Margaret Smith	AA/Cornell University	mes25@cornell.edu
Meg Oeller	FDA/CVM	moeller@cvm.fda.gov
Paul Bowser	NRSP-7/Cornell	prb4@crnell.edu
Ron Griffith	NRSP-7/Iowa State	rgriffit@iastate.edu
Thomas Vickroy	NRSP-7/U FL	vickroy@vetmed.ufl.edu

ADMINISTRATIVE REPORTS

REPORT FROM THE ADMINISTRATIVE ADVISORS - Dr. John Baker (Chair)

Dr. Baker began his report with a reminder to the Regional Coordinators to go to the NIMSS (National Information Management and Support System) site and complete the Appendix E forms required of participants of AES programs. The Appendix E form is critical for the estimation of FTE dedicated to each program.

In discussing the appointment of Dr. Bret Hess as the new Administrative Advisor for the Western Region, Dr. Baker noted the diligence with which the Western AES group acted upon this appointment.

Dr. Baker praised the Regional Coordinators for all of their efforts to increase the program funding and to put the program on a more stable funding situation. Among those issues to continue pursuing, he listed movement into an IR-4 like competitive grants program at NIFA and the development of an action plan roadmap to carry out this objective.

In conclusion, Dr. Baker stressed the need to develop a broader listing of stakeholder groups to align with additional NIFA priorities of sustainable agriculture and support of the rural, family farms.

REPORT FROM THE NATIONAL COORDINATOR – Dr. John G. Babish

Proposed changes to the program

Some personnel changes have occurred. Dr. Thomas Vickroy of the University of Florida, who is in attendance, will be assuming the position of Regional Coordinator for the Southern Region. Also, Dr. John Bake has assumed the position of Chair of the Administrative Advisors.

Dr. Bret W. Hess, Associate Dean and Director AES, University of Wyoming (brethess@uwyo.ed) has replaced Dr. David Thawley as Administrative Advisor in the Western Region. Dr. Hess' research efforts have focused on nutritional management strategies to improve production efficiency of forage-fed ruminant animals, with primary emphasis on strategic supplementation regimes and secondary interest in alternative forages. This change has been made in concert with the appointment of Dr. Zhanjiang

(John) Liu, Alumni Professor and Director, Department of Fisheries and Allied Aquacultures and Program of Cell and Molecular Biosciences, and Director, Aquatic Genomics Unit, Auburn University, as the Administrative Advisor for the Southern Region replacing Dr. Garry Adams.

ACTION ITEMS DISCUSSED

FENBENDAZOLE IN PHEASANTS

Need to get product development meeting scheduled.

1. Tom and Lisa to look at Target Animal Safety (TAS) data and make sure that there were not any problems with the pheasants.
2. Tom and Lisa to look at TAS protocol and see what should be asked as a exclusion for the next TAS study during product development meeting. If we need to do the TAS study (and it is not to our advantage to wait for the PD meeting, then we could try to do this part of the study this summer). We could essentially do it the same as the lasalocid TAS study. I know this is not ideal but Ron can comment on whether or not he has money he needs to spend regardless so minimizing what we do might not necessarily be necessary if it gets this part of the study done and allows us to get tissues to plan for the HFS and efficacy study the next summer. We would essentially be doing the fenbendazole study without protocol concurrence but would be modeling the study after the lasalocid TAS that had protocol concurrence. A worst-case scenario is that we will have more data than less.
3. Product Development meeting: Ask for efficacy data to be admissible; touch base about partial method validation.
4. Meg/Dorothy: Get data from current INAD to support efficacy and discuss efficacy study with McFarlan about efficacy
5. UC Davis to get assay up and running during 2010. Product development meeting ask if method validation is still acceptable.
6. Ron G.: Get samples during summer of 2010 for Davis to work with
7. Tom V.: Check with Brett Herrig (brent.herrig@sp.intervet.com) about designation? Not sure if this use has been formally designated at CVM.
8. Tom V. (Southern Region): Target this summer for submission of protocols (HFS for sure; do we do TAS this summer without protocol concurrence)?
9. Potential study to apply for Minor Use Minor Species grant
10. Summer 2011: Studies for Human Food Safety and Efficacy.

LASALOCID IN GAME BIRDS

1. U of F: Generate questions relative to the fact that the columns can no longer be purchased for the “official method”
2. Meg: Request a conference call with CVM
3. Note: Lisa Tell and Scott Wetzlich would like to attend conference call also
4. Ron: TAS technical support will be submitted
5. Ron: What happened to samples for TAS (1x, 3x and 5x?)
6. Efficacy: Georgia investigators are writing technical report. Report has been written and QAed, but investigators need to respond to QA issues. This may be a good one for having a pre-submission conference call with CVM due to some QA issues.
7. HFS: Still waiting for assay to be validated.

TULTHROMYCIN IN GOATS:

1. TAS submitted to CVM by Kris Clothier/Ron Griffith.
2. Efficacy: Lisa to do literature search regarding plasma and lung secretions correlations
3. Efficacy: Marilyn to get information to us regarding Office of Research studies
4. Efficacy: Tom to send information about diffusion method
5. Efficacy: Lisa to do PK modeling of serum data for Kris to provide new AUC's for data that was generated with rerun of diluted samples
6. Ron and Kris: Work on isolate information. MIC/AUC needs to be substantiated with kill kinetics (5 isolates)
7. HFS: Western region to get method validation written
8. HFS: Western region to finish tissue data analysis and gather data and send it to ISU
9. Lisa to follow up with Albert about designation
10. Doc 152: Dorothy or Meg to start working on FOI Summary

CIDRS GOAT AND DEER

1. Western region to send goat data from Fall 2009 to ISU. ISU grad student who is doing HFS (meat) report will also work on compilation of efficacy data.
2. Goat HFS: To be submitted by ISU (grad student working on it currently). NOTE TO RON: Need to submit an interpretation/summary of the method validation from Dennis. Even though he gives all of the information for meat method validation, he needs to give them a summary of what was done and what it meant.
3. Both UC Davis and ISU to get ready for Fall 2010 efficacy work with goats
4. Lisa: Follow up on foreign data information for deer. Meg already has HFS data. Efficacy will need to be done in US. Need to see if we can get TAS data.

OTHER BUSINESS

Fall Meeting

It was tentatively decided to hold the annual fall meeting in Rockville, MD on September 20/21st on the condition of coordinating lobbying efforts at that time. The final decision on the timing of the meeting will be made when the budget situation becomes clearer. This will be followed on a month-to-month basis and discussed at our monthly teleconferences.

There being no further business, the meeting was adjourned at 12:30 pm.

RESPECTFULLY SUBMITTED:
John G. Babish, Ph.D. Date: 6/12/10
Minor Use Animal Drug Program/NRSP-7 National Coordinator