MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 SPRING MEETING 2011
NOVEMBER 1ST, 2011

TUESDAY NOVEMBER 1ST, 2011

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its semi-annual fall meeting of the technical committee and administrative advisors on November 1st by teleconference starting at noon and hosted by the FDA Center for Veterinary Medicine (CVM), 7519 Standish Place, Rockville, MD

ATTENDANCE

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

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 present were Drs. John C. Baker (Michigan State University AES), Chairman of Administrative Advisors and Margaret Smith (Cornell University, AES). The attending USDA representative was Dr. Gary Sherman (Washington, DC) and the FDA liaisons were Drs. Meg Oeller and Dorothy Bailey (Rockville, MD).

12:00 PM INTRODUCTIONS

Introductions and meeting organization

Dr. John G. Babish started the meeting with a thank you to Dr. Bailey for her organizing efforts at FDA/CVM to have the teleconference conducted through the Adobe Connect facilities at Rockville, MD. The National Coordinator then outlined the agenda of the meeting with reports from the Regional Coordinators and presentations from FDA/CVM, NIFA, AA and National Coordinator.

Welcome from Dr. Meg Oller for Dr. Bernadette Dunham

Dr. Oller welcomed all to the teleconference on behalf of Dr. Bernadette Dunham, the Director of the FDA Center for Veterinary Medicine. She underscored the budget difficulties Dr. Dunham spoke of at the spring meeting and further 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.

REPORTS FROM THE REGIONS

WESTERN – DR. LISA TELL

Active Regional Projects:

ADR#325 – Florfenicol (Nuflor® Injectable Solution) for sheep for respiratory disease

The human food safety (HFS) 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. The data from the HFS study has been organized and a technical report has been written. The final technical report for the human food safety study was reviewed for Quality Assurance in March 2010. This report was submitted to FDA/CVM in July, 2010. On February 11, 2011, FDA/CVM concluded that the tissue residue depletion study was acceptable for supporting a withdrawal period determination, and assigned a 42-day withdrawal period. Other comments from FDA/CVM were that microbial food safety issues still need to be addressed which include the impact of florfenicol on antimicrobial resistance among bacteria of public health concern in or on treated sheep as well as human intestinal flora.

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. This study is currently pending and will not progress until CVM provides further guidance.

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

This project has been transferred to the Northeastern Region.

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* is 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. The final environmental assessment report for erythromycin in salmonids was completed in May, 2010 and submitted to FDA/CVM for review. The results of this environmental assessment report supports the safe use of erythromycin thiocyanate in all freshwater-reared salmonids at a dose regimen of 100 mg/kg bodyweight/day for 21 to 20 days. Christine Moffitt (author) submitted the White Paper for erythromycin. This was revised and submitted to FDA/CVM in July, 2010. We received notification January 12, 2011 from FDA/CVM that the Final Study Report for the pivotal Daphnia magna chronic toxicity study entitled: “Chronic toxicity of erythromycin thiocyanate to Daphnia magna in a flow-through, continuous exposure test system” is considered complete. Dr. Oeller is working on the White Paper for this study.

Collaborative Projects:

ADR#280 - Fenbendazole in Game Birds (Pheasants, bobwhite quail, partridge)

A conference call with Merck/Intervet/SP was held on February 25, 2010. A product development meeting was held with CVM on September, 9, 2010 to discuss the development plan for investigating the use of fenbendazole Type A medicated article for the treatment of nematode parasites in pheasants. The HFS protocol was submitted and received concurrence from CVM on 12/08/2010. The TAS study protocol was submitted to FDA/CVM for review in February 2011. Plans are in place to conduct the HFS and TAS studies in the summer of 2011. The Western region will perform the analytical testing of the samples. We have begun to re-establish the fenbendazole tissue method for pheasants by testing intra and inter-day precision

and accuracy. We are testing liver, muscle (breast and thigh), and skin/fat. In addition to spiked samples we will assay incurred samples to verify the method. *There were a total of 366 samples analyzed in our laboratory during the summer of 2011 (120 study; 138 stability; 108 validation). The analytical portion of the human food safety report has been written and submitted to Dr. Griffith at Iowa State University.*

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. All of the raw data from the UC Davis portion of this project was submitted to the Study Sponsor, Dr. Ron Griffith in August, 2010. The CIDR Efficacy study was initiated in August, 2010. *A letter dated August 12, 2011 from FDA/CVM stated that the human food safety requirements for the use of CIDR-G in goats have been satisfied for toxicology, residue chemistry, and microbial food safety. The Human Food Safety technical section is complete as of August 12, 2011. A withdrawal period was established as zero and a milk discard time of zero.*

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 HFS study have been analyzed and the PK data has been generated. Tissue samples from the HFS study (205) have been analyzed. The method validation report has been submitted to the Central Region for quality assurance review. See North Central region report for further information. Tissue samples to re-establish data for freezer stability have been run and the data submitted to Dr. Griffith of the North Central region. *A total of 102 freezer stability samples from Iowa State University were analyzed. The analytical data for the Human Food Safety Report has been provided to Dr. Kris Clothier and Dr. Ronald Griffith at Iowa State University.*

Other Projects/Activities:

Quality Assurance: Nothing to report.

Excede in Sheep*:* Study has been completed in domestic sheep. The serum samples have been analyzed and the pharmacokinetic data modeled. The data was presented at the UC Davis Veterinary Medical Teaching Hospital House Officers Research Seminar day on March 18, 2011.

Flunixin in Goats: Two cross over studies have been completed in domestic goats evaluating IV vs. IM administration. In addition, a pilot study has been completed in lactating goats. All samples are waiting to be analyzed due to challenges with the method.

Ceftiofur for Treating *Arcanobacterium pyogenes* Respiratory Infections in Deer: 27 isolates from deer (4 females, 7 males, and 6 unknown sex) ranging from 6 weeks to 14 years of age have been collected. Of these isolates, the MIC's for ceftiofur ranged from 0.25-1. All of

the isolates were sensitive to ceftiofur. Dr. Albert Ramudo from Pfizer was contacted on November 12th, 2009 regarding Pfizer's interest in a label claim. 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. The sensitivity data were compiled and have been published.

CIDRs for Deer: Historical conference call with Dr. Albert Ramudo. At this time, Pfizer has indicated that they are not interested in pursuing a label claim for deer.

New Projects:

Pharmacokinetics of tulathromycin in dairy goats: *A UC Davis summer student, Bernadette Grismer, performed this study. A total of 448 samples (328 milk; 120 plasma) were analyzed during the summer of 2011.*

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:

We will be working to establish and validate the flunixin analytical method for plasma samples from goats. In addition, we will process any samples relative to the tulathromycin in goats efficacy study.

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 which 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

Progress of the work and principal accomplishments:

Species Grouping Project:

INAD 10-320 Oxytetracycline in Fish
INAD 10-823 Romet-30 in Fish
INAD 11-145 Florfenicol in Fish

Efforts on this project consisted of providing administrative support and oversight 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.

Ovadine (Western Chemical) Disinfection of Fish Eggs:

We have been an evaluation of the efficacy of Ovadine (PVP-Iodine, Western Chemical) as an egg disinfection compound for fish eggs with a particular emphasis on the reduction of Viral Hemorrhagic Septicemia Genotype IVb from walleye eggs. Our trial will build on preliminary efforts, funded by New York Sea Grant Program, in which we found that the consensus treatment protocol of the Great Lakes Fishery Commission (50 mg/L iodine for 30 minutes) was not completely effective in the elimination of VHSV IVb. A disinfection trial was conducted during the 2010 walleye spawning season with the collaboration of the New York State Department of Environmental Conservation. Treatments included iodine doses of 0, 50 and 100 mg/L for 30 minutes. One publication on this work has been published and a second publication is in development.

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 (Florfeniol).

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

We anticipate our efforts on this project to center around the continued provision of administrative support and oversight 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.

Ovadine (PVP-Iodine, Western Chemical) Disinfection of Fish Eggs

Data from the Ovadine work is being summarized for publication. We are also investigating the potential of indexing Ovadine.

Strontium Marking of Fish Otoliths

We are in the early stages of developing a project to complete the data package needed to obtain a label or to index the use of Strontium Chloride for marking fish otoliths.

Allicin for the reduction of Aeromonas salmonicida infection in salmonids

We were approached by Dr. George Ketola of the USGS Tunison Laboratory of Aquatic Sciences, Cortland, NY about a potential project to evaluate the ability of allicin, a garlic extract, to reduce the severity of various pathogens of fish. We initiated a collaborative project in which we are evaluating the ability of the allicin to reduce the severity of Aeromonas salmonicida infection in rainbow trout. Dr. Ketola has had a long career of fish nutrition research (the former name of the Cortland facility was the USFWS Tunison Fish Nutrition Laboratory) that spans well over 30 years. In this collaboration, Dr. Ketola formulates the rations and we utilize our biosecure fish research laboratories for the conduct of the challenge trials. The effort will serve as the Master of Science thesis research for Dr. Kate E. Breyer, who is a Resident in the Laboratory Animal Medicine Program at Cornell. She is pursuing the MS degree through the Cornell University Employee Degree Program. Thus, her salary support is from sources other than NRSP7. Our efforts to date have focused on the development of the standard bacterial challenge model to achieve an appropriate level of Aeromonas salmonicida infection. Once the challenge model is established, we will proceed with the experimental trial in which allicin will be formulated into the ration at various concentrations in an effort to determine the effective dose to reduce the bacterial infection.

Given the financial limitation we are facing in the NE Region NRSP7, this collaboration between the Tunison Laboratory of Aquatic Sciences and the Laboratory Animal Medicine Program at Cornell is seen as an extremely economic means to conduct this research.

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.

(C) Use of Ovadine for the reduction of Viral Hemorrhagic Septicemia Virus on fish eggs.

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.

3) 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.

North Central – Dr. Ronald W. Griffith

Progress of the work and principal accomplishments

Goat CIDR-G Tissue Residue

Study report has been submitted. Mean tissue levels of progesterone 12 hours after CIDR removal were significantly lower than tissue levels in control does without CIDRs.

Goat CIDR-G Effectiveness

This study is in full swing. We have received excellent cooperation from producers in a number of states. We currently have over 600 dairy goats enrolled in the study in Iowa, California, Missouri, Minnesota and Wisconsin. On the meat goat side, we have two herds in Iowa and one at Texas A&M Prairieview that have participated. In the fall of 2011, we should have a herd at Florida A&M University and other group of goats at TAMU and possibly a small group of does in Iowa. Target for completion of the in-life phase is 2013.

Lasalocid in Pheasants Efficacy

The study was completed in 2007 and the study report submitted this summer. Undergoing final stages of review. Keeping fingers crossed.

Lasalocid in Pheasants TAS

A second high-dose group study was completed in July. The study report is currently being prepared.

Draxxin Target Animal Safety in Goats

The study report has been submitted to the FDA/CVM. Dr. Kris Clothier has a manuscript accepted by the Journal of Pharmacology and Therapeutics.

Draxxin Tissue Residue

Study report undergoing QA audit.

Draxxin Efficacy in Goats

PK/PD studies and MIC and killing kinetics data have been obtained. A partial study report on efficacy is being prepared. A manuscript is being prepared. A field trial may be necessary to complete this section.

Fenbendazole TAS in Pheasants

Protocol has been submitted to ONADE and is under final review. Birds are scheduled to arrive the third week in May.

Fenbendazole HFS

Working with the Lisa Tell in the Western Region on this project. Protocol concurrence has been received. On track to complete in-life phase in late summer or early fall.

Fenbendazole Reproductive Safety

We have received two summers' worth of hatching data from MacFarlane Pheasants and have requested data be kept for the coming hatching season. They have also provided data comparing hatching data of their own pheasant eggs with those of other producers that were hatched in MacFarlane's incubators. New England flock?

Ivermectin Cattle Fever Tick Efficacy

Working in conjunction with Tom Vickroy in the Southern Region. A preliminary draft of a protocol for this study has been circulated for review. Dr. Beto de Leon has responded with some comments and corrections. We are waiting to receive the right of reference from Merial. The preliminary study being conducted by Dr. Davey is in its 31's week. Apparently, the

sentinel cattle are still picking up ticks but the treated cattle remain free. It may be difficult to find sufficient numbers of ticky pastures in the northern region where *R. annulatus* is the species of tick. There are plenty of ticky pastures in the Southern region where *R. microplus* is the species of tick.

SOUTHERN – DR. THOMAS VICKROY

Overview of Projects in Progress

1. **ADR#352: Ivermectin Efficacy against Cattle Fever Tick in southern Texas**

This is a collaborative project among multiple entities, including the North-Central and Southern regions of NRSP-7, USDA-ARS and APHIS. This project is classified as a minor use project owing to the small number of affected animals and the relatively restricted geographical region that is impacted. A protocol was drafted by Dr. Ron Griffith and following revision was submitted to FDA -ONADE in July, which responded with a letter of non-concurrence in September. The primary role of the Southern region will be analytical testing of ivermectin in feed blocks that will be used for drug delivery to cattle in pastures. At this time, we have made necessary modifications of the approved regulatory method for ivermectin analysis in cattle liver in order to determine ivermectin content of a proprietary medicated feed block mixture (molasses/protein/mineral bovine supplement) that is formulated by Postive Feeds. We are in the midst of (1) conducting studies to validate the method for submission to FDA for possible concurrence and (2) using the analytical method to determine the level and consistency of drug content in the formulated feed blocks.

2. **ADR#279: Lasalocid for Coccidiosis in Pheasants**

This is a collaborative project between the North-Central and Southern regions. The role of the Southern region will be to carry out drug analyses of all tissue samples. Previous attempts to establish the approved regulatory method were unsuccessful and led to failure of a previous trial. However, we have now solved all of the analytical problems and have a robust and reliable working method that entails what are considered (by me) to be slight and non- significant modifications of the regulatory method that is approved for use in cattle liver and other tissues. This is a significant and requisite step that puts us in position to analyze samples from upcoming in-life phase of studies. At present, we are conducting work to validate this method and, once complete, will submit the work to FDA for evaluation. The goal is to obtain method concurrence prior to the initiation of in-life phase studies by the North-Central region.

3. **ADR#280: Fenbendazole in Game Birds** (pheasants, bobwhite quail, partridge) This is a collaborative project among the North-Central, Western and Southern regions. At this time, there is no recent progress to report.

Update on Other Programmatic Efforts and Changes

1. NRSP-7 Website: The Southern Region is responsible for maintaining and updating the NRSP-7 website, including MUMsRx and the RUSTi system for tracking the status of regional projects. In addition, the Southern Region coordinator organizes and coordinates monthly teleconferences among the regional coordinators and administrators. The next teleconference is scheduled tentatively for 6 December 2011 at 12:00pm EST.

2. Anticipated Use of Project Outcomes: The findings from all of the studies above will be utilized to fulfill the data requirements for Public Master Files and, ultimately, for FDA/CVM approval of these drugs for use in minor species.

PRESENTATIONS

Grismer B, Rowe JD, Carlson J, Wetzlich S, Kieu H, Tell L. Pharmacokinetics of a single subcutaneous injection of tulathromycin in lactating dairy goats (*Capra hircus*). UC Davis STAR student presentation, September 24, 2011

Leavens TL, Tell LA, Clothier KA, Griffith RW, Baynes RE, Riviere JE. Development of physiologically based pharmacokinetic (PBPK) model to predict tulathromycin distribution in goats. The Toxicologist, 50th Annual Meeting of the Society of Toxicology Annual Meeting, Washington DC, Vol 120(2), March 2011.

Rivera S, Tell L. Pharmacokinetics of ceftiofur crystalline free acid in sheep following subcutaneous single-dose administration. Proceedings of the 33rd Annual House Officer Seminar Day, VMTH, University of California Davis, Large Animal/Avian-Exotics/Lab Animal/Primate Presentations, March 11, 2011.

PUBLICATIONS

Doré E, Angelos JA, Rowe JD, Carlson JL, Wetzlich SE, Kieu HT, Tell LA. Pharmacokinetics of ceftiofur crystalline free acid after single subcutaneous administration in lactating and nonlactating domestic goats (*Capra aegagrus hircus*). J Vet Pharmacol Ther, 34(1):25-30, 2011.

Emily R. Cornwell, Geoffrey H. Groocock, Rodman G. Getchell, and Paul R. Bowser. 2010. Residual tannic acid destroys virucidal properties of iodine. North American Journal of Aquaculture 73(1):8-12.

Romanet J, Smith GW, Leavens TL, Baynes RE, Wetzlich SE, Riviere JE, Tell, LA. Pharmacokinetics and tissue elimination of tulathromycin following subcutaneous administration in meat goats. In preparation. Planned submission to AJVR, 2011.

Tell LA, Brooks JW, Lintner V, Matthews T, Kariyawasam S. Antimicrobial susceptibility of Arcanobacterium pyogenes isolated from the lungs of white-tailed deer (Odocoileus virginianus) with pneumonia. J Vet Diagn Invest, 23(5):1009-1013, 2011.

Topic Popovic, N., T. Howell, J.G. Babish and P.R. Bowser. 2011. Cross-sectional study of hepatic CYP1A and CYP3A enzymes in sunshine bass, channel catfish and Nile tilapia following oxytetracycline treatment. Research in Veterinary Science. In press.

Young G, Smith GW, Leavens TL, Wetzlich SE, Baynes RE, Mason SE, Riviere JE, Tell LA. Pharmacokinetics of tulathromycin following subcutaneous administration in meat goats. Res Vet Sci, 90(3):477-479, 2011.

REPORTS FROM LIAISONS

NIFA/USDA – Dr. Gary Sherman

Dr. Gary Sherman continued his discussion from spring on the funding methods of the program and the complexities of the budget process. A previous vote taken by the Technical Committee following this spring 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". He presented rather positive news on the ability of NIFA to move the MUADP from the Congressional "earmarks" category of Other Funding to a competitive, non-earmark category. He noted that NIFA simply needs to refrain from requesting that the MUADP be "noncompetitive" to remove the earmark label and therefore garner stronger Congressional support. Dr. Sherman also restated his remarks from previous teleconferences

that the USDA Special Grants category in which the MUADP exists does not require noncompetitive grant status.

REPORT FROM FDA/CVM - Drs. Meg Oller and Dorothy Bailey
As with previous meetings, 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. Continuing with discussions of regional projects, Dr. Bailey reviewed a table (see below) with the Regional Coordinators on the progress of MUADP submissions to FDA/CVM.

REPORT FROM THE ADMINISTRATIVE ADVISORS - Dr. John Baker (Chair)
Dr. Baker began his report praising the Regional Coordinators for their efforts, Dr. Baker questioned how long the Program could be expected to function under the current funding circumstances of delayed payments to regions and insufficient funds. He went on to suggest possible movement into a competitive grants program within the AES framework and the development of an action plan roadmap to carry out this objective.

He praised the Regional Coordinators for their heroic efforts to keep current projects moving from protocol development to FDA/CVM submission. In his remarks he suggested the possibility of looking at historical projects that could have species added with lower costs than totally new projects. In these cases, the savings would largely be in the shortened time for the development of analytical methods. It was brought up, however, that transfer of analytical methodology across species is not always a straightforward affair.

Once again, 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
AES approved funding of NRSP-7 for $335,000. These funds will be appropriated from Hatch monies out of the FY12 budget, which has not yet been approved by Congress. Final Federal FY12 Budget will not be forthcoming until the Super Committee completes its mission. It is difficult to estimate what the outcome will be with the action of the SC. It is likely they will not accomplish their mission and an automatic series of draconian budget cuts will go into place. RC should be sure that the communications between their colleges and AES are more fluid than they have been in the past to ensure a more rapid transfer of funds.

Attempts to generate more stakeholder involvement to get behind the FY Farm Bill. Facebook and Google+ efforts are underway. Headquarters has been developing experience in marking through these channels. It is necessary to be able to get your story out through press releases as well as these Social Media sites. Press releases can be done relatively inexpensively (~$129 to $550) through PR Newswire. Desperate need to get our situation out to the world. A copy of the Facebook web site was presented to the attendees (see below).

Enter competitive grants program. NIFA – Discussion of Gary's points on the structure of the grants and organization. AES – Not been done before and a lot of new ground to break here. I have a concern that funds for a competitive program would be treated fragile and likely to disappear when other funds are in short supply.

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date
I-011389 (CIDR/ Goats)	P-0007	4/15/09	Milk Residue Study	Study accepted 10/9/09
	E-0011	7/6/09	Tissue Residue Study Protocol	Protocol concurrence 8/12/09
	E-0012	7/9/09	Revised Effectiveness Study Protocol	Protocol concurrence 9/11/09
	P-0018	11/18/10	Tissue Residue Study	HFS Technical Section Complete 8/12/11
I-006013 (Erythromycin/ Salmonids)	P-0109	9/24/08	Annual Report	Report acceptable 5/22/09
	P-0111	12/3/09	*Daphnia magna* Chronic Toxicity Study	Incomplete 6/2/10
	P-0113	7/16/10	Environmental Assessment	Incomplete 4/3/11 Currently working ONADE to address insufficiencies.
	P-0114	8/4/10	Response to *Daphnia magna* Incomplete Letter	Study data accepted for use in EA 1/12/11
I-010062 (Fenbendazole/ Game Birds)	P-0012	5/7/09	Residue Depletion Study (partridges)	Study unacceptable 11/5/09
	P-0013	6/24/09	Residue Depletion Study (pheasants)	Study unacceptable 12/3/09
	E-0016	11/3/10	Tissue Residue Study Protocol (pheasants)	Protocol concurrence 1/11/11 Study completed, preparing to submit final study report to CVM
	E-0021	2/17/11	Target Animal Safety Study Protocol (pheasants)	Protocol Concurrence 5/4/11 Study completed, preparing to submit final study report to CVM

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date
I-011836 (Nuflor Gold/ sheep)	E-0003	9/4/09	Tissue Residue Study Protocol	Requested CVM to stop review (10/23/09) based on discussions with HFV-150 (wait to submit protocol until after presubmission conference Z-0005)
	P-0010	8/20/10	Tissue Residue Study (Study conducted with Nuflor, not Nuflor Gold. CVM said the study could be submitted to Nuflor Gold INAD in Z-0005 MOC)	Study accepted 2/11/11
I-009096 (Lasalocid/ pheasants)	E-0009	4/7/08	Target Animal Safety Study Protocol	Protocol non-concurrence 5/28/08
	E-0010	3/26/09	Revised Target Animal Safety Study Protocol	Protocol concurrence 6/9/09 Study completed, preparing to submit final study report to CVM
	P-0013	7/1/10	Effectiveness Study	Technical Section Complete 3/25/11
I-010536 (Strontium chloride/ salmonids)	P-0011	10/16/08	Annual Report	Report acceptable 4/9/09
	P-0015	8/16/10	Annual Report	Report acceptable 1/28/11
I-011512 (Tulathromycin/ Goats)	P-0012	5/20/10	Target Animal Safety Study	Technical section complete 11/5/10
I-010766 (Lincomycin/ Honey Bees)	P-0010	2/25/09	Residue Depletion Study	HFS technical section complete 6/11/09
	P-0011	12/7/09	Effectiveness Study	EFF technical section complete 6/4/10

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date
	P-0017	8/27/10	Request for Environmental Technical Section Complete	ENV technical section complete 11/2/10
I-012056 (Ivermectin block/minor use in cattle in south Texas)	E-0002	7/7/11	Effectiveness Study Protocol	Protocol non-concurrence 9/2/11 Currently conducting pilot effectiveness study with USDA
PMF 005947 (CIDR/ Sheep)	A-0000	3/2/09	Request CVM to establish PMF for CIDR in sheep	PMF established 7/8/09
PMF 005988 (Lincomycin/ Honey Bees)	A-0000	12/13/10	Request CVM to establish PMF for lincomycin in honey bees for American foulbrood	PMF established 6/24/11

P = data; E = protocol

Handout of Facebook Page under development

OTHER BUSINESS
Scheduling of stakeholder support for supporting the inclusion of the MUADP funding in the

SPRING Meeting
It was tentatively decided to hold the annual spring meeting in Rockville, MD with the date of the meeting conditioned upon coordinating lobbing 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: 12/22/11
Minor Use Animal Drug Program/NRSP-7 National Coordinator