DRAFT MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 SPRING MEETING 2012
NOVEMBER 6ST, 2012 (NOON TO 3:30 PM)

TUESDAY NOVEMBER 6ST, 2012

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (MUADP/NRSP-7) held its semi-annual fall meeting of the technical committee and administrative advisors on November 6st 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	dorothy.bailey@fda.hhs.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	margaret.oeller@ fda.hhs.gov
Paul R. Bowser	MUADP/NRSP-7/Cornell U	prb4@cornell.edu
Ron Griffith	MUADP/NRSP-7/Iowa State	rgriffit@iastate.edu
Thomas Vickroy	MUADP/NRSP-7/U FL	vickroy@vetmed.ufl.edu

The MUADP/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 (AA) and Margaret Smith (Cornell University, AES). The attending NIFA representative was Dr. Gary Sherman (Washington, DC) and the FDA liaisons were Drs. Meg Oeller and Dorothy Bailey (Rockville, MD). Absent were administrative advisors Drs. John Liu (Southern Region) and Frances D. Galey (Western Region).

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.

REPORTS FROM THE REGIONS

NORTHEAST REGION: DR. PAUL BOWSER

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 evaluating 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 press.

Allicin for the reduction of Aeromonas salmonicida infection in salmonids:

We are conducting a cooperative project with the USGS Tunison Laboratory of Aquatic Science in which we are evaluating the use of allicin as a nutritional supplement for the reduction of *Aeromonas salmonicida* in salmonids. We have developed a challenge model with *A. salmonicida* in rainbow trout and conducted the first trial.

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 with one publication and a second manuscript in press. We are 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. Our protocol is under review by CVM FDA.

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. 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.

To date we have developed a standard bacterial challenge model to achieve an appropriate level of *Aeromonas salmonicida* infection following an IP challenge. This was followed by the first trial. Prior to the trial, for 14 days the fish were fed a diet in which allicin was added at 0.0, 0.5, 1.0 or 2.0% of the diet by weight. Fish were fed at 2% body weight per day. In this trial we did not observe a benefit from the addition of allicin to the diet at 0.0, 0.5, 1.0 or 2.0% of the diet when fish were fed at 2% of body weight per day. This protocol was based on a protocol reported in the literature in which the challenge pathogen was *Aeromonas hyhdrophila*. We will be repeating this trial to confirm the results of the first trial. If we again observe a lack of effect, we may continue the effort, but with a challenge that involves a water borne challenge with the bacterium.

Publications issued or manuscripts approved during the year: (**see "Principal Publications" at end of report)**

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 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.

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 (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 have 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. Update 5/1/2012: Contacted CVM to see if isolates from other regional sections would be acceptable to get final concurrence for the efficacy section of this project. Awaiting advice from CVM regarding how to move forward on this project.

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. Update 5/1/2012: Awaiting advice from CVM regarding how to move forward on this project or abort this project and go back to Nuflor Injectable Solution project.

ADR#299 - Pirlimycin for Dairy Goats

Project on hold until funding is identified and CIDR goat studies are completed.

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. Update 5/1/2012: Awaiting final amendment of EA by CVM.

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. Update 5/1/2012: Waiting confirmation to be able to submit this study to CVM after QA audit at ISU.

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. Update 5/1/2012: Awaiting update from Casandra Plummer to see if we need to enroll additional California dairy goats in the study summer of 2012.

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. Update 5/1/2012: Currently working on putting the final report together for submission to CVM.

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. Update 5/1/2012: Manuscript in preparation.

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. Update 5/1/2012: This method has been validated for goats and cattle. Three of the four sets of goat samples have been analyzed. One set of the goat samples remain to be analyzed and two sets of milk samples.

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. Update 5/1/2012: Manuscript in preparation.

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 milk and tissue 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.

NORTH CENTRAL – DR. RONALD W. GRIFFITH

Progress of Work and Principal Accomplishments:

Active Regional Projects:

Goat CIDR-G Effectiveness

The study report is in preparation. We have received excellent cooperation from producers in a number of states. There were 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. We had planned on having more meat-type goats in the study this fall but all of the sites we identified were unable to participate due to lower than expected numbers of breeding females. We contacted smaller herds in Iowa, but they have also reduced numbers. CIDRs seem to be in widespread use in the goat population now that they are readily available for sheep.

Lasalocid in Pheasants TAS

The study report has been submitted to the FDA/CVM.

Draxxin Tissue Residue

The study report is nearing submission.

Draxxin Efficacy in Goats

Trying to figure out what type of study will be acceptable to the FDA/CVM to demonstrate efficacy.

Fenbendazole HFS

The study report has been submitted for QA audit and should be submitted to the FDA/CVM soon.

Fenbendazole TAS in Pheasants

The study report is in the final stages of preparation and, hopefully, will be submitted for a QA audit very soon. The study was completed in August, 2011. There were some slight differences in the clinical pathology findings but the birds gained weight well, there were no abnormal findings on gross necropsy or histopath, and there were no detectable feathering abnormalities.

Fenbendazole Reproductive Safety

We have received three summers' worth of hatching data from MacFarlane Pheasants and the data have been submitted to Dorothy Bailey. Fertility drops off dramatically as the egg-laying season progresses but there does not appear to be an effect from feeding 100 ppm fenbendazole to the hens. MacFarlane Pheasants has also provided data comparing hatching data of their own pheasant eggs with those of other producers that were hatched in MacFarlane's incubators. This information will be included as part of the Target Animal Safety study.

Ivermectin Cattle Fever Tick Efficacy

Working in conjunction with Tom Vickroy in the Southern Region and a whole host of individuals with the Texas Animal Health Commission, the USDA-APHIS and the Cattle Fever Tick Eradication Program. A study protocol was submitted to ONADE but we received a letter of non-concurrence. The biggest problems are the non-uniformity of the product (how to analyze for potency) and the lack of a precise description of exactly how the product was going to be used and the expected outcomes. The study protocol was altered in accordance with the ONADE comments and it was decided to proceed with the two infested herds under the revised study protocol. Two tick-infested herds were identified. One herd in South Texas which was infested with *Rhipicephalus microplus* began treatment in November, 2011 and treatment is continuing at this time. Ivermectin has virtually eliminated any tick infestion on treated cattle in that herd. Treatment of the second herd infested with *Rhipicephalus annulatus* began in April 2012 and no results are available at this time.

Pregnant Mare Serum Gonadotrophin-ADR 0353

A request was received to investigate the feasibility of performing studies to support FDA/CVM approval for Pregnant Mare Serum Gonadotropin to be used as a reproductive aid in small ruminants. A current review of the literature is being prepared with the goal of subsequently requesting a product development conference.

SOUTHERN – DR. THOMAS VICKROY

Progress of Work and Principal Accomplishments:

Active Regional Projects:

1. Lasalocid for Treatment of Coccidiosis in Pheasants (ADR#279)

This pending project is a collaborative effort between the North-Central Region (Iowa State University) and the Southern Region (University of Florida) of MUADP. The primary role of the Southern region is to carry out drug analyses of all tissue samples. Previously, attempts to bridge the approved regulatory method for lasalocid analysis in bovine liver were unsuccessful in liver or skin from pheasants, which led to the failure of a human food safety trial. However, we have now solved all of the analytical problems and have a robust and reliable working method. That method has undergone a partial validation in samples of liver and skin with adhering fat from pheasants. In view of the previous difficulties in mounting a working analytical method, the validated method was submitted to the CVM along with the protocol for the in-life phase of studies. Pending CVM review and concurrence with the study protocol and the analytical method, this project will be in position to move forward with the in-life phase studies in the North-Central Region. The anticipated time line for project start up is October of 2012.

2. Ivermectin Medicated Feed Block for Control of Cattle Fever Tick in South Texas (ADR#352)

Preliminary work has continued slowly on this project. The study represents a minor use in a major food animal species and is a collaborative effort among several agencies and institutions, including the North-Central Region (Iowa State University) and the Southern Region (University of Florida) of the MUADP as well as USDA-ARS and APHIS. The project has not yet received concurrence from the CVM and it is unclear whether it will proceed or be completed. The primary role of the Southern Region is to conduct analytical testing of ivermectin levels in medicated feed blocks that are formulated by Postive Feeds, Inc. These blocks, which will be used for drug delivery to cattle in pastures, contain a complex mixture of nutrients, minerals and numerous other ingredients, including molasses as a taste enhancer. We have been successful in adapting the approved regulatory method for ivermectin analysis in order to determine ivermectin levels in the feed blocks. At this time, we have completed analysis of three batches of medicated blocks, each containing 16 to 24 individual blocks. Work is currently in progress as we continue to analyze medicated blocks for consistency of drug levels.

3. Fenbendazole in Game Birds (ADR#280)

This is a collaborative project among the North-Central, Western and Southern regions. The Southern Region has no principal role related to in-life studies (North-Central Region) nor the analytical phase (Western Region), so any progress updates will be contained in those regional reports.

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 June 2012.

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

Breyer, K.E., R.G. Getchell, G.H. Groocock, L.L. Coffee, G.A. Wooster, P.R. Bowser, H..G. Ketola. 2012. Garlic (Allicin): More Than Just Flavor For Your Fish! 37th Annual Eastern Fish Health Workshop. Lake Placid, New York. 23-27 April 2012.

PUBLICATIONS

Clothier, K. A., Leavens, T., Griffith, R. W., Wetzlich, S. E., Baynes, R. E., Riviere, J. E., and Tell, L. A. (2012) Tulathromycin assay validation and tissue residues after single and multiple subcutaneous injections in domestic goats (Capra aegagrus hircus), *J Vet Pharmacol Ther 35*, 113-120.

Dechant, J. E., Rowe, J. D., Byrne, B. A., Wetzlich, S. E., Kieu, H. T., and Tell, L. A. (2012) Pharmacokinetics of ceftiofur crystalline free acid after single and multiple subcutaneous administrations in healthy alpacas (*Vicugna pacos*), *J Vet Pharmacol Ther*. (In Press)

Groocock, G.H., Getchell, R.G., Cornwell, E.R. Frattini, S.A., Wooster, G.A. and Bowser, P.R. (2012) Iodophor Disinfection of Walleye Eggs Exposed to Viral Hemorrhagic Septicemia Virus type IVb. North American Journal of Aquaculture. (In Press)

Leavens, T. L., Tell, L. A., Clothier, K. A., Griffith, R. W., Baynes, R. E., and Riviere, J. E. (2012) Development of a physiologically based pharmacokinetic model to predict tulathromycin distribution in goats, *J Vet Pharmacol Ther 35*, 121-131.

Topic Popovic, N., T. Howell, J.G. Babish and P.R. Bowser. 2012. Cross-sectional study of hepatic CYP1A and CYP3A enzymes in sunshine bass, channel catfish and Nile tilapia following oxytetracycline treatment. Research in Veterinary Science 93:283-291

REPORTS FROM LIAISONS

REPORT FROM FDA/CVM - Drs. Meg Oeller and Dorothy Bailey

What's Up at FDA/CVM?

1. Approval of Lincomycin
   1.1. Technical Section Complete
2. Effectiveness Erythromycin
3. GFI 61 Update
4. PMF – new procedures
5. Problems with Erythromycin CMC
6. Collaboration with OR on goat projects – Draxxin, Banamine?

MUADP Stats Update

1. Current MUADP Goat Projects
   1.1. Active Projects:
      1.1.1. Intravaginal progesterone
      1.1.2. Tulathromycin/respiratory infections
   1.2. Future Projects:
      1.2.1. Flunixin?

2. Current MUADP Cattle Project
   2.1. Project in progress:
      2.1.1. Ivermectin medicated feed blocks for Cattle Fever Ticks
         2.1.1.1. Effectiveness trial in progress (pivotal?)
         2.1.1.2. Right of reference pending?
3. Current MUADP Sheep Projects
   3.1. Projects in progress:
      3.1.1. Florfenicol (Nuflor & Nuflor Gold) - respiratory infections
      3.1.2. Tulathromycin - respiratory infections
      3.1.3. Excede
4. Current MUADP Gamebird Projects
   4.1. In Progress:
      4.1.1. Fenbendazole:
         4.1.1.1. Pheasants
         4.1.1.2. partridges (later)
         4.1.1.3. quail (later)
      4.1.2. Lasalocid – pheasants
5. Current MUADP Fish Projects
   5.1. Erythromycin/BKD/salmonids
   5.2. Species grouping studies
   5.3. Strontium chloride /marking/finfish
   5.4. PVP iodine – fish eggs
   5.5. Allicin- antibacterial/immunostimulant
6. Erythromycin/Salmonids Status
   6.1. Effectiveness – complete
   6.2. Target Animal Safety – complete
   6.3. Human Food Safety – complete
   6.4. Environmental Safety – EA for CVM review due – 8/22/2012
   6.5. PMF to publish after EA accepted
   6.6. Pharmaceutical co. – manufacturing – Can we help?
7. MUADP Misc Projects
   7.1. Honey bees:
      7.1.1. Lincomycin/American foulbrood - Approved!
   7.2. Rabbits: Ivermectin/ear mites??
8. On Hold?
   8.1. For Goats:
      8.1.1. Pirlimycin for mastitis
      8.1.2. Sprectramast for mastitis
   8.2. For Fish: CCP for spawning
   8.3. For Deer:
      8.3.1. Fenbendazole for GI parasites
      8.3.2. Lasalocid for coccidiosis
   8.4. For Ornamental Fish:
      8.4.1. GnRHa & Domperidone for spawning
      8.4.2. Metomidate for anesthesia
9. Pending MUADP Work
   9.1. Revise $SrCl_2$ TAS Protocol
   9.2. AB resistance submissions for Draxxin
   9.3. Ivermectin – TAS/HFS/EA negotiation after “right of reference”
   9.4. Florfenicol project clarification
   9.5. Coordinate OR & MUADP research

9.6. Complete Erythro PMF
9.7. Identify and post all Complete Technical Sections on PMF Web page

NIFA/USDA – Dr. Gary Sherman

Dr. Gary Sherman again continued his discussion from fall on the funding methods of the program and the complexities of the budget process. Before the meeting, it was requested Dr. Sherman delve into Senate FY-13 NIFA budget details to determine if MUADP might be buried somewhere within a composite line. At the time of our last call, offical Senate markup information, vetted by NIFA, was not yet available, though there were several unofficial versions circulating which NIFA does not comment on. Taken together, the Senate budget information and explanations below allow me to conclude that MUADP is not embedded anywhere within the FY13 Senate mark-up. 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 THE ADMINISTRATIVE ADVISORS - Dr. John Baker (Chair)

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

Dr. Babish reported that he had learned that MUADP will not have an amendment to the Farm Bill ready in time for the Chairwoman's mark. MUADP strategy will be adjusted as a result. Barring any shenanigans or sabotage, the Senate version of the Farm Bill will pass out of the Committee soon. Majority Leader Reid will schedule the bill for Senate floor action sometime between now and when 112th congress adjourns. Whatever that period of time is will be our window of opportunity to advance MUADP in the Senate. I welcome your insights and thoughts about the proposed strategy. I will be calling upon you for your help in the coming weeks.

Senate path forward:

1) pursuit of a Senate bill to formally authorize MUADP (this could be attached as an amendment to the Senate Farm Bill on the floor).
2) pursuit of an amendment to Senate Farm Bill when it goes to the floor.
    - Senate target is Sen. Amy Klobuchar (D-MN). Should she not champion the bill/amendment then I will move on to the next potential champion.

House path forward:

1) pursuit of a House bill to formally authorize MUADP (this could be included in the Chairman's mark).
2) if that fails then seek to include the provision in the House Farm Bill in the amendment phase.
3) if that fails then seek to have it included in the floor debate.
4) if that succeeds then we'd urge the senate to recede to the House to adopt the MUADP provision.
    - House target is Rep. Dennis Cardoza (D-CA-18). He has expressed interest. His staff has assured me that they are working on it.

Minor Use Producer Testimonials

It would be tremendously helpful to have testimonials from producers of minor species about the importance of the program. Do we have statements from goat farmers, honey bee producers, game bird farmers, etc. about the importance of having certain drugs available all due to MUADP efforts?

If we could have a prominent catfish farmer say his successful operation is reliant upon sulfadimethoxine and florfenicol for which MUADP secured the approvals for this could be the linchpin in securing the backing of the delegations from Mississippi, Louisiana, and Alabama. The same can be said for the other minor species.

OTHER BUSINESS

NONE BROUGHT FORWARD

FALL Meeting

It was tentatively decided to schedule the fall meeting in concert with the outcome of the Farm Bill and delay setting a date or location. 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 2:30 pm.

RESPECTFULLY SUBMITTED:
John G. Babish, Ph.D. Date: 6/15/12
Minor Use Animal Drug Program/NRSP-7 National Coordinator