MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 SPRING MEETING 2013
April 18th 2013 (Noon to 3:30 pm)

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (MUADP/NRSP-7) held its semi-annual spring meeting of the technical committee and administrative advisors on Thursday, April 18th, 20013 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
Amy Omer	FDA/CVM	Amy.Omer@fda.hhs.gov
Gary Sherman	USDA/CSRESS	gsherman@nifa.usda.gov
John G. 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
Phil Elzer (AA)	AA/LSU Ag Center	Pelzer@agcenter.lsu.edu
Rod Getchell	MUADP/NRSP-7/Cornell U	rgg4@cornell.edu
Ron Griffith	MUADP/NRSP-7/Iowa State	rgriffit@iastate.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. 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), Margaret Smith (Cornell University, AES) and Phil Elzer (LSU, AES). The attending NIFA representative was Dr. Gary Sherman (Washington, DC) and the FDA liaisons were Drs. Meg Oeller and Amy Omer (Rockville, MD). Absent wer administrative advisor Dr. Frances D. Galey (Western Region) and Regional Coordinator Thomas Vickroy (Southern Region).

12:00 PM INTRODUCTIONS
Introductions and meeting organization

Dr. John G. Babish started the meeting with a thank you to Drs. Omar and Bailey for their 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 NIFA/USDA, the Regional Coordinators, FDA/CVM, Administrative Advisors and National Coordinator.

NIFA/USDA – Dr. Gary Sherman
1). Historically, MUADP/NRSP-7 enjoyed line item Special Grant funding from Congress (administered under NIFA's special grant authority) but this ended 3 years ago when 'earmarks' were greatly reduced.

2) MUADP/NRSP-7 is currently supported by Hatch funding. It was by virtue of the Program's legitimacy as an NRSP that, when special grant funding ended, there was a secondary (Hatch) Authority under which some funding could be made available to the program, at the discretion of the directors of the system of US Agricultural Experiment Stations (AESs).

3) NIFA and Congress continue to support and fund the Hatch program. The Hatch Act authority provides funds to be distributed by NIFA on a formula basis to Ag Experiment Stations co-located at Land Grant colleges and universities. NRSPs and MultiState Committees, proposed and administered by AES Directors, are supported as a specified apportionment from

Hatch funds. AES directors determine levels of funding for NRSPs and Multi-State Committees based on available funds.

4) NIFA Budget cuts for 2013 include loss of $180 M in mandatory funding that was not renewed, and the effects of Sequester. The ~18% overall cut to NIFA is expected to be applied roughly evenly across all NIFA programs. The Hatch program will likely experience this % decrease and this should be expected to impact Hatch sub-programming like NRSPs.

5) Efforts continue to search for a Western Region Administrative advisor for NRSP-7

6) NIFA is cognizant of the exploratory efforts underway related to a possible merger with IR-4. The Agency will consider consensus restructuring possibilities if and when the leaderships of both NRSP-7 and IR-4/NRSP-4 come to one or more mutually agreed upon potential merger strategy(ies).

7) Dr. Sherman, NIFA Liaison to NRSP-7, reminded the group that Secretary Vilsack and President Obama continue to strongly support revitalization of rural America. It is therefore appropriate to emphasize the roll of the MUADP in supporting a diversified, growing and vibrant rural economy.

REPORTS FROM THE REGIONS

WESTERN – DR. LISA TELL

Progress of Work and Principal Accomplishments:

Active Regional Projects:

ADR#325/INAD 10-958 – 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. Update 04/2013: No new progress 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 04/2130: No new progress on this 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 04/2013: 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). Update 04/2013: HFS report received concurrence from CVM, April 2014.

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 04/2013: Nothing new to report.

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 04/2013: In March, 2013 an ERA amendment was requested by CVM for the HFS technical report but this study will result in a technical section incomplete due to some analytical challenges and freezer stability requirements.

Other Projects/Activities:

Quality Assurance: Since the Fall of 2012, we had a FDA Inspection and our efforts have been focused on addressing SOP revisions and internal operations.

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 completed. Manuscript being resubmitted to another journal as JVPT would only accept as a brief communication.

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. Update 11/2012: This method has been validated for goats and cattle. All of the samples have been analyzed. Manuscript in preparation.

Another study is being initiated to evaluate flunixin use in goats and milk residues.

Plasma samples from a goat study study lead by Jamie Boehmer at the Office of Research evaluating inflammatory markers and flunixin are currently being analyzed. Dr. Tell is in contact with Dr. Boehmer to get this study published.

Tulathromycin pharmacokinetics in dairy goats: A UC Davis summer student, Bernadette Grismer, performed this study. A total of 448 samples (328 milk; 120 plasma) have been analyzed. Update 04/2013: Manuscript complete. Submission in process.

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:

Goat banamine milk residue study (non GLP), tulathromycin multidose goat study (non GLP), and get all protocols and SOPs in order and accordance with FDA Fall 2012 audit.

Manuscripts and Abstracts: Submitted, Accepted or Published Since the Last Meeting:
None.

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 still in preparation.

Lasalocid in Pheasants Target Animal Safety
We have a technical section incomplete letter from ONADE. The problems should be correctable and re-submission of an amended report is scheduled. The work has been published in the Avian Diseases journal.

Lasalocid in Pheasants Human Food Safety
The study protocol for the in-life phase at Iowa State was submitted from the Southern Region and we have received protocol concurrence. The FDA had questions on the analytical method and we had planned to complete method validation beginning in June, 2013. The method validation is on-hold pending guidance from the FDA primarily concerning requirements for a quality assurance unit. It probably will not be possible to complete the method validation this year.

Draxxin Tissue Residue

ONADE asked for additional data and clarification for the study report. The Western Region is leading the response effort.

Draxxin Efficacy in Goats

This is now largely in the hands of the FDA/CVM.

Fenbendazole Human Food Safety in Pheasants

The Western and North Central Regions combined to do this study. We were recently informed that this technical section is complete.

Fenbendazole Target Animal Safety in Pheasants

We received a technical section incomplete letter on the study report. Additional data, clarification and justification of study procedures will be necessary. The reproductive safety portion of the work was not acceptable but the label will just state that reproductive safety has not been demonstrated. A paper covering this work and the reproductive safety data has been submitted to Avian Diseases.

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 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 the ticks appear to have been completely eradicated from those animals and the pasture they were on. Treatment of a second herd infested with *Rhipicephalus annulatus* began in April 2012. Bulls were added to that herd after the start of the treatment regimen in the cows. The bulls were not ingesting the medicated protein/mineral blocks and remained infested for a period of time during the early breeding season. However, this herd and pasture is now considered to be free of cattle fever ticks.. A study at a third herd will begin when the tick burden becomes high enough. The quarantine zone remains under extreme drought conditions. We are planning on having a quality assurance monitor re-visit the project and do a more extensive monitoring of the study. The right of reference from Merial is remains unresolved.

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. No further action at this point.

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. Two manuscripts on this work have been published in the peer-reviewed literature.

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.

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.

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.

SOUTHERN – DR. THOMAS VICKROY

Progress of Work and Principal Accomplishments:

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

This project is a collaborative effort between the North-Central Region (Iowa State University) and the Southern Region (University of Florida) of MUADP. A tissue residue depletion study protocol (number 2012-235-HFS) was submitted in September to the INAD exemption file for a project to investigate the use of lasalocid (Avatec®) Type A medicated article for the control of coccidiosis associated with infection by *Eimeria colchici*, *E. duodenalis* or *E. phasiani* in pheasants. The protocol is currently under review with a response expected within the next one to two weeks. If approved, the study will be performed jointly by the North-Central and Southern regions. The in-life phase of studies will be conducted at Iowa State under the supervision of Dr. Ron Griffith and the Southern Region will carry out marker (lasaloicd) residue analyses of all tissue samples. Pending CVM concurrence with the study protocol and the analytical method, this project is tentatively set to begin with the in-life phase studies in late Spring of 2013.

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

This 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. Preliminary work at the Southern Region has continued on this project, although the project faces several major hurdles before it can be considered for possible concurrence by the CVM. The primary role of the Southern Region has been to determine levels of ivermectin in medicated feed blocks that are formulated by the Texas-based company Postive Feeds, Inc. These blocks, which will be used for oral drug delivery to free-range cattle in pastures, contain a complex mixture of nutrients, minerals and numerous other ingredients, including molasses as a taste enhancer. We have adapted the approved regulatory method for ivermectin analysis to determine ivermectin levels in formulated feed blocks. During the past six months, we have continued to determine ivermectin content in block samples from different lots of medicated blocks. Based on our preliminary work, it appears that Postive Feeds has developed a manufacturing process that yields fairly consistent drug levels throughout the block matrix, although work continues on that front.

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 helps organize monthly teleconferences among the regional coordinators and administrators. The next teleconference is scheduled to be held in May 2013.

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.

Summary Review of Progress

1. *Work accomplished under the original project - t*he objective of this program is to conduct safety, efficacy or residue-related studies that facilitate drug clearances (tolerances, exemptions and registrations)for minor and specialty food animal species. This work is conducted in cooperation with appropriate state, federal and industry personnel to (a) determine and prioritize minor-use needs and data requirements, (b) review, analyze and evaluate minor-use species research proposals, (c) develop and organize data for minor-use animal species drug registrations, and (d) prepare and submit petitions for drug registrations.

2. *The degree to which objectives have been met* – Relative to the aforementioned objectives, considerable progress has been made for each of the active projects listed above. However, the degree to which these objectives have been met varies from project to project. 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 Southern 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.

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

1. Topic Popovic, N., Howell, T., Babish, J. G., and Bowser, P. R. (2012) Cross-sectional study of hepatic CYP1A and CYP3A enzymes in hybrid striped bass, channel catfish and Nile tilapia following oxytetracycline treatment, Res Vet Sci 92, 283-291.

2. Tell, L. A., Stephens, K., Teague, S. V., Pinkerton, K. E., and Raabe, O. G. (2012) Study of nebulization delivery of aerosolized fluorescent microspheres to the avian respiratory tract, Avian Dis 56, 381-386.

3. Romanet, J., Smith, G. W., Leavens, T. L., Baynes, R. E., Wetzlich, S. E., Riviere, J. E., and Tell, L. A. (2012) Pharmacokinetics and tissue elimination of tulathromycin following subcutaneous administration in meat goats, Am J Vet Res 73, 1634-1640.

4. Mehl, M. L., Tell, L., Kyles, A. E., Chen, Y. J., Craigmill, A., and Gregory, C. R. (2012) Pharmacokinetics and pharmacodynamics of A77 1726 and leflunomide in domestic cats, J Vet Pharmacol Ther 35, 139-146.

5. Lee, K. A., Tell, L. A., and Mohr, F. C. (2012) Inflammatory markers following acute fuel oil exposure or bacterial lipopolysaccharide in mallard ducks (Anas platyrhynchos), Avian Dis 56, 704-710.

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REPORTS FROM LIAISONS

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 shared his outline of a proposed evaluation for merging the IR-4 Minor Use Pesticide Program with the Minor Use Animal Drug Program. These steps were presented in the outline form below to the group.

Merging the MUADP/NRSP-7 into the IR-4 Minor Use Pesticide Program in Three Steps

Relationship #1

MUADP and IR-4 Share Some Resources – Primary goal is to develop a greater understanding of the working of the two organizations

MUADP Include pesticides into the Mission Statement as below

- To identify animal drug and pesticide 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.

Action Items:

1. Identify immediate and long-term pesticide needs for minor species.
2. MUADP and IR-4 Establish Informal Relationship between MUADP Regional Coordinators and IR-4 GLP units.
    a. Identify IR-4 GLP units capable of performing audits and reviews of current studies
    b. Can the IR-4 GLP units satisfy FDA/CVM requirements for MUADP
    c. Costing of IR-4 GLP audits
3. Identify RFPs to fund a joint drug/pesticide program
4. Continue efforts to incorporate both programs into the FY 12 Farm Bill
5. Establish relationship with shareholders of a joint program
6. Make decision on moving to #2 or #3 below in 3 months and incorporate this decision into the MUADP renewal plans.

Relationship #2

MUADP and IR-4 Begin integration of work
Modify Mission Statement accordingly

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

Action Items:

1. MUADP and IR-4 develop a list of potential animal pesticide projects for FDA/CVM and EPA approvals
2. MUADP establishes contacts at EPA
3. Assessment of protocols and resources necessary to begin the merger of the two programs
4. Explore AES and NIFA mechanisms for joining the programs.

Relationship #3

Complete inclusion of pesticides into the Mission Statement

- To identify animal drug and pesticide needs for minor species and minor uses in major species,
- To generate and disseminate data for safe and effective therapeutic applications of drugs and pesticides, and

- To facilitate FDA/CVM and EPA approvals for drugs and pesticides identified as a priority for a minor species or minor use.

Action Items:

1. MUADP and IR-4 more forward on either or both AES and NIFA paths for funding.

OTHER BUSINESS

NONE BROUGHT FORWARD

FALL Meeting

The final decision on the timing of the meeting will be made when the federal budget situation becomes clearer and discussed at monthly teleconferences.

As there was no further business, the meeting was adjourned at 2:45 pm.

RESPECTFULLY SUBMITTED:
John G. Babish, Ph.D. Date: 6/30/13
Minor Use Animal Drug Program/NRSP-7 National Coordinator