MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 SPRING MEETING 2011
MARCH 31ST AND APRIL 1ST, 2011

THURSDAY MARCH 31ST, 2011

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its annual spring meeting of the technical committee and administrative advisors on March 31st and April 1st at the FDA Center for Veterinary Medicine (CVM), 7519 Standish Place, Rockville, MD

ATTENDANCE AM MEETING

NAME	AFFILIATION	EMAIL ADDRESS
Bernadette Dunham	FDA/CVM	Bernadette.dunham@fda.hhs.gov
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The NRSP-7 technical committee is made up of a National Coordinator, four Regional Coordinators, four regional Administrative Advisors, and liaisons from USDA and FDA. The National Coordinator is Dr. John Babish (Cornell University). The Regional Coordinators are Dr. Lisa Tell (University of California, Davis), Dr. Thomas Vickroy (University of Florida), Dr. Ronald Griffith (Iowa State University), and Dr. Paul Bowser (Cornell University). The Administrative Advisors present are Drs. John C. Baker (Michigan State University AES), Chairman of Administrative Advisors and Francis D. Galey (University of Wyoming). The USDA representative is Dr. Gary Sherman (Washington, DC) and the FDA liaisons are Drs. Meg Oeller and Dorothy Bailey (Rockville, MD).

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

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

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

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

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

REPORTS FROM LIAISONS

USDA/NIFA – Dr. Gary Sherman

Dr. Gary Sherman continued his discussion from fall 2010 on the funding methods of the program and the complexities of the budget process. A vote taken by the Technical Committee following this discussion of the MUADP funding category was unanimous to have Dr. Sherman work in concert with the Technical Committee to move the program's current status from noncompetitive to competitive within NIFA/USDA. It was felt that this move would be necessary to support increased funding and maintain viability in the current political climate that discourages Congressional "earmarks".

Dr. Sherman's presentation is, in part, incorporated below.

Vision - A new MUADP operational paradigm, administrative structure and corresponding authority that further optimizes the Program's capability and capacity to achieve its scientific goals, and meet the needs of stakeholders, partners and the consuming public, by:

1. Shifting to Federal implementation of MUADP as a nationally competitive grants program (to promote program productivity and ensure ongoing access to the most qualified scientists, and to the best laboratory resources and institutional partnerships)
2. Identifying either an existing NIFA legislative authority or proposing a new program-specific authority that will efficiently support the implementation of MUADP as a productive competitive program
3. Expanding total program funding sufficiently to:
    a. Enable adequate throughput of promising new minor species drugs
    b. Permit second tier (re)competition for regionally awarded program funds, thereby engaging more LGUs as direct program participants and partners.
    c. Support a National HQ to coordinate expanding program activities
4. Establishing an independent stakeholder advisory/advocacy committee

Potential Mechanisms to Pursue

A. Shifting to Federal implementation of MUADP as a nationally competitive grants program (to promote program productivity and ensure ongoing access to the most qualified scientists, and to the best laboratory resources and institutional partnerships).

- a. Scenario:
    - i. Propose competitive administrative model (done - 2009)
    - ii. Receive input/comment on proposal from NIFAs Policy Branch – Pending (following FY-11 budget final action and after congressional language is reviewed)

iii. Receive approval (or not) from NIFA Senior Leadership to administer as competitive program (Model after Critical Issues (CI) Program initially)

B. Identifying either an existing NIFA legislative authority or proposing a new program-specific authority that will efficiently support the implementation of MUADP as a productive competitive program *[these options considered in conjunction with I above]*

a. Authority Options:
   i. Use existing NIFA authority
   ii. Retain under existing (earmark) authority
   iii. Critical Issues Program model (under same current authority and recently converted to competitive administration)
   iv. NIFA Policy section leaning this way presently, may be most expedient
   v. This is the authority traditional earmarks are administered under (guilt by association?)
   vi. Draft a new Program-specific authority – typically requires Congressional action, change of legislation supported by grassroots advocacy (Timeline: entirely dependent on effectiveness of advocacy)

C. Expanding total program funding sufficiently to:
   a. Enable adequate throughput of promising new minor species drugs
   b. (Eventually) permit consideration of second tier (re)competition for regionally awarded program funds, thereby engaging more LGUs as direct program participants and partners.
   c. (Eventually) support a National HQ to coordinate expanding program activities
   d. Scenario:
      i. Ongoing : Requires Congressional action to raise appropriations. Active stakeholder support and promotion is critical (Timeline: entirely dependent on effectiveness of advocacy efforts)

D. Establishing an independent stakeholder advisory/advocacy committee
   a. Scenario:
      i. Ongoing facilitation
      ii. Self perpetuating
      iii. Internal leadership
      iv. More voices to support efforts to enact new authorization and or change authority

Optimal Scenario:

A. Advocacy multiplication and synergy
   a. MUADP PDs and their Institutional advocates
   b. Effective stakeholder Advisory Group
   c. Professional associations (e.g., AVMA, AAVMC)
   d. Other advocates (APLU)?
   e. Routinely make “polished” case to Senate and House Ag Committee members – Focus on Congress (80%), USDA (10%), and OMB (10%)
   f. Restructure as competitive program
   g. Propose MUADP reform to NIFA
   h. NIFA considers/approves (a normal budget year would facilitate)
   i. Implement competition next grant cycle after approval

B. . Continue advocacy emphasizing that the program is now *“nationally competitive”* (and so <u>functionally</u> distinct from earmarks)

a. All states may now compete for MUADP funding
b. All states benefit from improved minor species production success
c. Set a more compelling stage for requests for:
    i. Additional funding to grow this competitive program
    ii. Drafting of a MUADP-specific authorization that removes MUADP from administrative association with the authority for all other Congressionally Directed line Items (earmarks)
    iii. Propose/establish language for dedicated authority for the "nationally competitive" MUADP

C. Once functionally AND administratively dissociated from earmarks MUADP should be viewed with greater favor by both Congress and USDA-NIFA.
D. Majority of advocacy efforts may now be focused on growing the appropriation toward a level that will support a National HQ along with greater opportunity for other LGUs to compete for funds, and greater overall program productivity (drug R&D throughput).
E. Re-competition of funds regionally can be unwieldy, inefficient and sometimes against regulation, depending on the circumstances and authorities involved. NIFA approval would be required and could not be guaranteed.

REPORTS FROM THE REGIONS

WESTERN – DR. LISA TELL

Progress of Work and Principal Accomplishments:

Active Western Region 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.

Acti ve 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. The analytical laboratory in the Western region has started 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.

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.

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. *Freezer stability of tulathromycin in goat tissues was assessed again to cover a 16 month time span. While the tulathromycin concentrations in the tissues were less than expected in the spiked tissues, incurred samples from both the Target Animal Safety and Human Food Safety studies have shown good stability. The data for the tissue samples freezer stability has been submitted to Dr. Griffith of the Northcentral region for the HFS report.*

Other Projects/Activities:

Quality Assurance: Nothing to report.

Ceftiofur (Excede) in Sheep*: Study has been completed 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.*

Cephapirin in Goats: *An analytical method for measuring cephapirin in goat serum samples was established in the Western Region analytical laboratory during this reporting period. 105 samples were analyzed from goats that were administered the drug intramammary. No detectable concentrations of cephapirin were found systemically.*

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 submitted to the Journal of Veterinary Diagnostic Investigation for publication. The reviewer's comments have been received and addressed. We are currently waiting on favorable acceptance of the manuscript based on the revisions.*

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. *Proposed discussion regarding this project at Spring 2011 Meeting.*

New Projects:
Moxidectin in Goats

Tulthromycin in Dairy Goats:
UC Davis summer student has been identified and funding for her position has been awarded.

Laboratory Report:
Most of the activity continues as establishing new analytical methods and sample analysis in the laboratory. Results and plans are reported under separate projects above.

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

Work Planned for Remainder of the Year: Over the next year our primary goals are to work on getting the fenbendazole game bird analytical method re-established in our laboratory and analyzing the samples from the Human Food Safety Study (summer of 2011). In addition, we will be working to get the flunixin analytical method for goats established in the laboratory.

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

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.

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:

1. To identify animal drug needs for minor species and minor uses in major species.
2. To generate and disseminate data for safe and effective therapeutic applications, and
3. 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

Progress of the work and principal accomplishments

1. **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 analysis of all tissue samples. Previous attempts to establish the approved regulatory method were unsuccessful, but will be a necessary pre-requisite before in-life phase of studies can move forward. Preliminary work on establishing and gaining concurrence for a robust and reliable analytical method was halted owing to a higher priority being assigned to the ivermectin project in cattle (ADR#352). Work on this project is slated to resume as quickly as time permits.

2. **ADR#280: Fenbendazole in Game Birds** (pheasants, bobwhite quail, partridge)

This is a collaborative project among the North-Central, Western and Southern regions. A conference call and product development meeting was held with CVM on 9 September 2010. A development plan was discussed for investigating the use of fenbendazole Type A-medicated article for the treatment of nematode parasitic infections in pheasants.

a) *HFS Protocol*: a protocol was drafted, reviewed by Western and North-Central Region Coordinators and submitted to CVM. The HFS protocol received concurrence from CVM on 8 December 2010. The in-life phase studies will be conducted at Iowa State and analytical studies will be conducted at UC Davis.
b) *TAS Study Protocol*: was submitted to FDA/CVM for review by ONADE in February 2011. Plans are in place to conduct TAS studies in the summer of 2011.
c) Reproductive Safety Studies: hatching data have been collected and will continue to be collected during the upcoming hatching season for pheasants at one site (McFarlane Farms in Wisconsin) . In addition, we have communicated with and established a second site to collect data for reproductive safety assessment (Mahantongo Farms in Pennsylvania).

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

This is a collaborative project among the North-Central and Southern regions of NRSP-7 that is classified as a minor use project owing to the small number of affected animals and the geographical isolation of the affected region. A preliminary draft of a protocol for this study has been circulated for review. Dr. Beto Perez de Leon has responded with some comments and corrections. We are waiting to receive the right of reference from Merial. A preliminary study being conducted by Dr. Davey is into week 31 and sentinel cattle are still picking up ticks while treated cattle remain tick free. Problems and obstacles remain including the limited number of pastures laden with *R. annulatus* in the northern region of the quarantine zone. The Southern region will be

responsible for analytical testing of samples and is currently working to establish and validate the approved regulatory method.

Update on Other Programmatic Efforts and Changes

1. Hiring of New Chemist: Mr. Kacy Magee, a chemist with several years of analytical experience, was hired in January of 2011. Mr. Magee has spent considerable effort bringing the lab into a state of GLP compliance and presently is working on the ivermectin analytical method in beef liver.

2. 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 2 May 2011 at 12:00pm.

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.

Work Planned

Over the next quarter our primary goals are to fully establish the ivermectin method for analysis of samples from the Texas cattle tick fever study and to return to our suspended effort of developing and gaining concurrence of a modified analytical method for lasalocid in pheasants. This will be essential for allowing studies to proceed in the North-Central region.

FRIDAY APRIL 1ST 2011

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

MEETING ATTENDEES

NAME	AFFILIATION	EMAIL ADDRESS
Gary Sherman	USDA/CSRESS	gsherman@nifa.usda.gov
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ADMINISTRATIVE REPORTS

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 at within the AES framework and the development of an action plan roadmap to carry out this objective.

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

Those active projects discussed included:

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

Following the review of regional projects, Dr. Dorothy Bailey presented her overview of project status within FDA/CVM. These status issues are summarized in the table below by INAD Number.

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date	Region(s)
I-011389 (CIDR/ Goats)	P-0007	4/15/09	Milk Residue Study	Study accepted 10/9/09	North Central & Western
	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	Pending (5/17/11 due date)	
I-006013 (Erythromycin/ Salmonids)	P-0109	9/24/08	Annual Report	Report acceptable 5/22/09	Western
	P-0111	12/3/09	*Daphnia magna* Chronic Toxicity Study	Incomplete 6/2/10	
	P-0113	7/16/10	Environmental Assessment	Pending (4/15/11 due	

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date	Region(s)
			ERA submitted 2/10/11	date)	
	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	Southern & North Central
	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	
	E-0021	2/17/11	Target Animal Safety Study Protocol (pheasants)	Pending (4/8/2011 due 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)	Western
	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 acceptable 2/11/11	
I-009096 (Lasalocid/ pheasants)	E-0009	4/7/08	Target Animal Safety Study Protocol	Protocol non-concurrence 5/28/08	North Central
	E-0010	3/26/09	Revised Target Animal Safety Study Protocol	Protocol concurrence 6/9/09	

INAD Number	Submission Number	Date Submitted	Submission Description	Outcome/ Date	Region(s)
	P-0013	7/1/10	Effectiveness Study	Effectiveness Technical Section Complete 2/25/11	
I-010536 (Strontium chloride/ salmonids)	P-0011	10/16/08	Annual Report	Report acceptable 4/9/09	Northeast
	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	TAS technical section complete 11/5/10	North Central
I-010766 (Lincomycin/ Honey Bees)	P-0010	2/25/09	Residue Depletion Study	HFS technical section complete 6/11/09	Western
	P-0011	12/7/09	Effectiveness Study	EFF technical section complete 6/4/10	
	P-0017	8/27/10	Request for Environmental Technical Section Complete	ENV technical section complete 11/2/10	
PMF 005947 (CIDR/ Sheep)	A-0000	3/2/09	Request CVM to establish PMF for CIDR in sheep	PMF established 7/8/09	North Central & Western
PMF 005988 (Lincomycin/ Honey Bees)	A-0000	12/13/10	Request CVM to establish PMF for lincomycin in honey bees for American foulbrood	Pending (6/12/11 due date)	Western

P = data; E = protocol

Presentations

Groocock, Geoffrey H., Emily R. Cornwell, Rodman G. Getchell, Gregory A. Wooster, Paul R. Bowser. 2010. Efficacy of iodophore disinfection of viral hemorrhagic septicemia virus (VHSV) on walleye (*Sander vitreus*) eggs. Annual Meeting of the New York Chapter of the American Fisheries Society. Lake George, New York. 10-12 February 2010.

Groocock, G.H., E.R. Cornwell, R.G. Getchell, G.A. Wooster, and P.R. Bowser. 2010. Iodophor Disinfection of Walleye (*Sander vitreus*) Eggs. 35th Eastern Fish Health Workshop. Shepherdstown, WV. 24-28 May 2010.

Manuscripts Submitted, Accepted or Published Since the Last Meeting:

Clothier, K. A., Leavens, T., Griffith, R. W., Wetzlich, S. E., Baynes, R. E., Riviere, J. E., and Tell, L. A. (2011) Tulathromycin assay validation and tissue residues after single and multiple subcutaneous injections in domestic goats (Capra aegagrus hircus), *J Vet Pharmacol Ther*. doi: 10.1111/j.1365-2885.2011.01300.x

Clothier, K. A., Leavens, T., Griffith, R. W., Wetzlich, S. E., Baynes, R. E., Riviere, J. E., and Tell, L. A. (2011) Pharmacokinetics of tulathromycin after single and multiple subcutaneous injections in domestic goats (Capra aegagrus hircus), *J Vet Pharmacol Ther 34*, 448-454.

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.

Leavens, T. L., Tell, L. A., Clothier, K. A., Griffith, R. W., Baynes, R. E., and Riviere, J. E. (2011) Development of a physiologically based pharmacokinetic model to predict tulathromycin distribution in goats, *J Vet Pharmacol Ther*. doi: 10.1111/j.1365-2885.2011.01304.x.

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

OTHER BUSINESS
None

Fall Meeting
It was tentatively decided to hold the annual fall meeting in Rockville, MD on September 20/21st on the condition of 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: 7/12/11
Minor Use Animal Drug Program/NRSP-7 National Coordinator