MINUTES
MINOR USE ANIMAL DRUG PROGRAM/NRSP-7 FALL MEETING 2009
NOVEMBER 19TH AND 20TH, 2009

THURSDAY NOVEMBER 19, 2009

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its semi-annual meeting of the technical committee and administrative advisors on November 19th and 20th at the FDA Center for Veterinary Medicine (CVM), 7519 Standish Place, Rockville, MD

ATTENDANCE AM MEETING

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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. Alistair Webb (University of Florida), Dr. Ronald Griffith (Iowa State University), and Dr. Paul Bowser (Cornell University). The Administrative Advisors are Dr. Margaret Smith (Cornell University), Dr. Garry Adams, Chairman of Administrative Advisors (Texas A&M), and Dr. John Baker (Michigan State University AES). The USDA representative is Dr. Gary Sherman (Washington, DC) and the FDA liaison is Dr. Meg Oeller (Rockville, MD).

9:00 – 12:00 INTRODUCTIONS

Introductions and meeting organization

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

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

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

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

Welcome from Dr. Bernadette Dunham

Dr. Dunham, the Director of the FDA Center for Veterinary Medicine (CVM) welcomed everyone and began the discussion about the future direction of the program. She stressed the need for collaboration with stakeholders and the need to demonstrate to the leaders at USDA and in the Congress the impact of the program on both animal health and public health. She recounted changes at FDA that mirror the need to focus on "One Health" initiatives that link animal and human health concerns. 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.

Dr. Dunham praised the program for its recent successes including the approval of the progesterone CIDR for out-of-season breeding of sheep. This product had been identified by the US sheep industry as their number one need.

The NRSP-7 program has a good story to tell. With extremely limited resources it has provided the data to support 28 drug approvals since the early 1980s. The species that it serves are an important part of US agriculture and will help to feed the world. The work of NRSP-7 helps assure the health of these animals and helps to ensure the safety of the food they produce. 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.

ADMINISTRATIVE REPORTS

Changes at the USDA

Dr. Gary Sherman described the funding methods of the program and the complexities of the budget process. He also described leadership and organizational changes at USDA. This includes the recent changes at the USDA Cooperative State Research,

Education, and Extension Service (CSREES). First of all, it is no longer CSREES. It is now NIFA, the National Institute of Food and Agriculture.

The new Research, Education, and Economics (REE) priorities of NIFA presented by Dr. Sherman included:

- Global Food Security and Hunger
  NIFA supports new science to boost U.S. agricultural production, improve global capacity to meet the growing food demand, and foster innovation in fighting hunger by addressing food security for vulnerable populations.
- Climate Change
  NIFA-funded projects create the scientific information needed so producers can plan and make decisions to adapt to changing environments and sustain economic vitality and can take advantage of emerging economic opportunities offered by climate change mitigation technologies.
- Sustainable Energy
  NIFA contributes to the President's goal of energy independence with a portfolio of grant programs to convert biomass to bio-fuels, design optimum biomass for bio-energy production, and produce value-added bio-based industrial products.
- Childhood Obesity
  NIFA-supported programs ensure that nutritious foods are affordable and available and that individuals and families are able to make informed, science-based decisions about their health and well-being.
- Food Safety
  NIFA food safety programs work to reduce the incidence of food-borne illness and provide a safer food supply by addressing and eliminating causes of microbial resistance to contaminants, educating consumer and food safety professionals, and developing food processing technologies.

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

12:00 – 1:00 Lunch

1:00 – 5:00
Discussion with the Human Food Safety Reviewers from CVM

The Regional Coordinators presented quick overviews of their on-going projects and then joined the CVM reviewers in a very helpful discussion of currently available guidance documents, the format of submissions for review, protocol development, and various problems with the use and validation of regulatory methods. This valuable exchange should benefit the program and the CVM reviewers through more efficient study plans and the production of more accessible reports to the agency. The committee truly appreciates the time and assistance provided by the reviewers.

Proposed changes to the program

Some personnel changes are imminent. Dr. Thomas Vickroy of the University of Florida will be assuming the position of Regional Coordinator for the Southern Region when Dr. Alistair Webb retires April 30, 2010. He attended this meeting to facilitate the transfer. Also, Dr. Garry Adams has a different appointment at Texas A&M and can no longer

serve as the Administrative Advisor for the Southern Region. This meeting was the last he will attend in that capacity. Dr. David Thawley, who could not attend, is also unable to continue as Advisor for the Western Region. Both of these positions should be filled in the near future. Dr. Margaret Smith, Advisor for the Northeast Region, began her tenure with the committee recently and was a welcome addition.

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

FRIDAY NOVEMBER 20TH, 2009 EXECUTIVE WORKING SESSION

9:00 – 2:00

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its second day of the fall 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
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Margaret Smith	AA/Cornell University	mes25@cornell.edu
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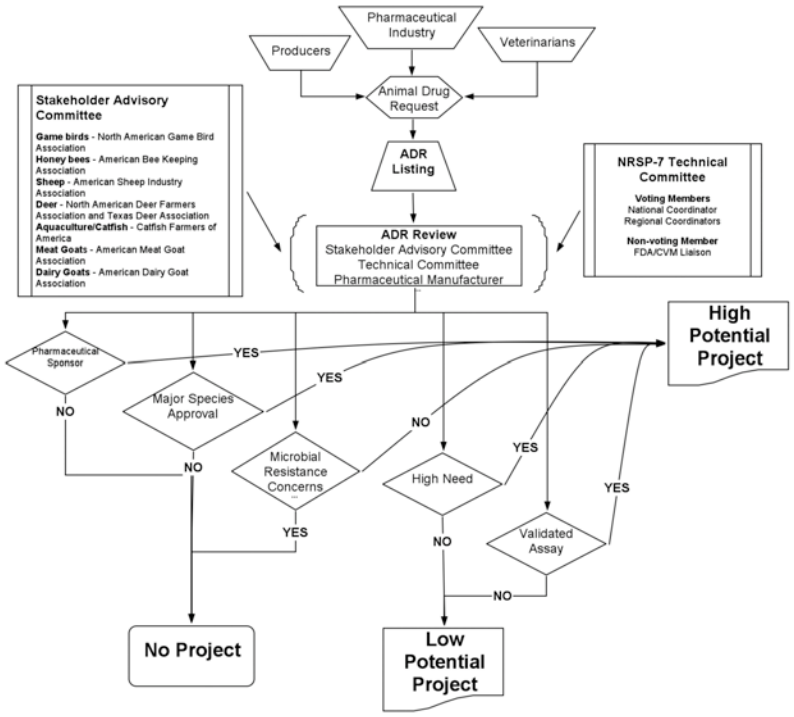
Prioritization and selection of projects for the Program

The process for selection of drugs for testing in NRSP-7 was reviewed. Filing of an Animal Drug Request (ADR) form by any group or individual associated with specialty animal production initiates the process. Representatives of such groups include, animal producers or their representative organizations, pharmaceutical manufacturers, university faculty and veterinarians. ADR request form can be submitted online at www.NRSP7.org or through any of the four Regional Drug Coordinators, the National Coordinator, and FDA/CVM liaison. Once received, the ADR is assigned a unique ADR number and included in the master ADR listing maintained at FDA/CVM, the National Coordinator's headquarters and at www.NRSP7.org.

During the spring annual meeting the NRSP-7 Technical Committee and representatives of the Stakeholder Advisory Committee (SAC) review the current projects and consider new ADR for funding. Each newly received ADR is then evaluated by the Technical

Committee and SAC according to established criteria that include (1) availability of a pharmaceutical manufacturing sponsor, (2) major species approval, (3) microbial resistance concerns, (4) significance to the animal industry, (5) cost of developing the necessary data, and (6) food safety implications. ADR requests that meet these criteria are considered as high or low potential projects. This process is schematically represented in Figure 1.

Figure 1. Flow chart outlining the process for selection of drugs for testing in the NRSP-7 Minor Use Animal Drug Program



ADMINISTRATIVE ADVISORS' REPORT

Closing Comments from the Chair of Administrative Advisors
Dr. Garry Adams outlined a series of observations from his four years as Chair of the Administrative Advisors and made several suggestions for growth of the Program.

In the area of progress

- Five-year review and approval was a major validation of the need for and successes of the Program;
- Annual Reports are a helpful and necessary to keep stakeholders abreast of events in the Program;
- The CIDR-G approval has provided the sheep industry with a much needed agent for expanding breeding throughout the year;
- Stakeholder Engagement has increased dramatically during the last five years as suggested in the previous five-year review;
- The MUADP draft White Paper provides a good blueprint for growth and development of the Program, but needs re-evaluation and feedback from stakeholders and funding agencies;

- FDA CVM engagement such as evidenced in this meeting are to be encouraged as the ultimate usefulness of the Program depends upon drug approvals as well as publications; and
- The need for the Program to be more active in legislative engagement has become critical over the last three years as noncompetitive grants are phased out of the budgeting process.

Constraints to path forward

- Rigid prioritization of resources is necessary to achieve 1.5 approvals in 5 years;
- Transition toward a more balanced targeted and competitive portfolio of awarded funds;
- Enhance integration of stakeholder-academia-government-pharma consortium or centers of excellence;
- Implement regular audits of all regional laboratories;
- Work with FDA to adhere to acceptable formats for all communications and submit as electronically searchable files;
- Convene stakeholder only meetings in the Midwest to establish a strong, working coalition of stakeholders;
- Expand candid dialog with FDA CVM reviewers to streamline the approval process and avoid misunderstanding of requirements; and
- Implement identical project management software in all regional laboratories.

REGIONAL COORDINATORS' REPORTS

Northeast Region: Dr. Paul Bowser

Progress of the work and principal accomplishments

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

Hydrogen Peroxide Project:

INAD 9493 Hydrogen Peroxide as a Therapeutic Compound for Bacterial Gill Disease in Fish.

No additional work has been performed on this project during this study period.

Species Grouping Project:

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

No additional work has been performed on this project during this study period.

Usefulness of the findings:

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

Work planned for next year:

Species Grouping Project:

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

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

Other:

We are also considering the development of a project that centers on the question of Iodophore disinfection of fish eggs to prevent the vertical transmission of Viral Hemorrhagic Septicemia Virus. Contact has been made with a potential sponsor, Western Chemical, which expressed interest in developing a collaboration with the NRSP7.

CRITICAL REVIEW (Northeast Region)

1) Work accomplished under the original project:

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

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

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

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

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

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

Incomplete work or areas needing further investigation:

The development of a crop (species) grouping concept is seen as imperative for supporting efforts to gain labels for therapeutic compounds for fish. Our work on

Oxytetracycline, Romet-30/Romet-TC and Aquaflor (Florfenicol) in fish is proposed to be part of an effort to utilize those compounds as models in this effort. We expect that our efforts in developing a species grouping concept for fish will be a major undertaking in the upcoming years.

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

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

North Central – Dr. Ronald W. Griffith

Progress of the work and principal accomplishments

Goat CIDR-G Milk Residue
Study report accepted. We have requested a zero-day withholding time for milk. If allowed, this will greatly enhance our ability to complete the efficacy study for milk goats.

Goat CIDR-G Tissue Residue
Validation of the analytical phase has been completed along with an ongoing freezer stability study of both incurred and spiked residues. Dr. Dennis Hallford at NMSU is performing the analytical work. The data indicate that P4 levels are stable to multiple freeze-thaw cycles as expected. Sixteen meat-type does were purchased and CIDR's placed in 8 does on October 24, 2009. The CIDR's were removed on November 11 and muscle and fat tissues harvested according to protocol (just less than 12 hr. following CIDR removal). The reproductive tracts were removed and examined by a board certified theriogenologist. The tissues were shipped to the analytical lab on November 17, 2009. Analysis for progesterone levels will be performed the week of November 23, 2009.

Goat CIDR-G Effectiveness
The NC and Western Regions are cooperating on this study. The Western Region is currently conducting a study in dairy goats with the U.C. Davis herd. Both regions decided to just do a single herd this fall and plan on a big push during next fall's breeding season. The NC (Iowa State) is working with a herd of 54 meat-type does. CIDR's were placed on October 9, 2009 and were removed on October 27, 2009. Estrus synchronization occurred in 90% of the does. Contacts have been made for placing CIDR's in at least 3 dairy goat herds in Wisconsin during the fall 2010 breeding season. We have one other group of meat goats lined up for next fall in Iowa and need to find at least one more herd. We still need to identify several more herds willing to cooperate with this study. Our targets are 6 herds of approximately 60 does each in at least two different geographic areas of the U.S. We need to do 6 herds for dairy goats and 6 herds for meat goats. Our target for submission of the completed study report is spring or summer 2011.

Draxxin Target Animal Safety in Goats
The QA report was recently received from Sandy Ogletree with some relatively minor corrections requested. The report should be submitted very soon. Dr. Kris Clothier has prepared a manuscript for submission to the Journal of Pharmacology and Therapeutics.

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

Draxxin Efficacy in Goats
A protocol based upon determination of AUC/MIC was prepared and submitted. It was decided that we needed some preliminary pharmacokinetic and MIC data in order to set a realistic target. We have procured sufficient isolates of *Mannheimia haemolytica* (over 30) but could use a few more isolates of *Pasteurella multocida.* We have placed a request for isolates on the American Association of Small Ruminant Practitioners list-serve and have contacted almost all the state diagnostic labs in the U.S. with a request for additional isolates of *Pasteurella*. Dr. Kris Clothier also presented a talk at the last US Animal Health Association meeting and requested isolates from that group. Preliminary data from 6 goats in the TAS study indicated that tulathromycin given subcutaneously is very rapidly absorbed. We have performed a larger pharmacokinetic study (using the 25- and 48-day goats of the HFS study above). Plasma samples were collected from these 10 goats with much earlier and more frequent sampling times. The plasma samples have been submitted to the analytical lab at U.C. Davis.

Lasalocid in Pheasants Efficacy
The study was completed in 2007 and the study report QA'd by Sandy Ogletree several months ago. There has been no reply to the quality assurance report or to requests for a reply.

Lasalocid in Pheasants TAS
The study was completed the first week of August, 2009. The study report has been written except for the section dealing with the statistical analysis. The student has promised to work on this over the Christmas break. There were no adverse effects noted when lasalocid was fed at 1X, 2X and 3X the highest recommended dose for chickens and turkeys. These levels of lasalocid were fed for 6 weeks.

Bioclip in Sheep
No report. Too many projects at the moment to devote any time to this for at least another month.

Western – Dr. Lisa Tell
Progress of Work and Principal Accomplishments

Active Regional Projects:
ADR#325 – Florfenicol (Nuflor® Injectable Solution) for sheep for respiratory disease
The human food safety and efficacy studies required by FDA/CVM for the old formulation of florfenicol (Nuflor Injectable Solution) have been completed. All of the data from this project have been published.

This project has been terminated and this termination has been entered into RUSTI.

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.

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

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

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

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

ADR# 311 –Lincomycin soluble powder for foulbrood disease in Honeybees
The human food safety technical section is complete. The pending section that needs to be written and submitted to CVM is the effectiveness technical section. Currently waiting for the investigator to write the technical report for FDA/CVM submission.

Collaborative Projects:

ADR# 258 - CIDRg (Controlled Internal Drug Release Devices) in Sheep
FDA/CVM has accepted all of the data for this study and the information has been summarized by FDA/CVM in a Public Master File. Completed sections are effectiveness, target animal safety, human food safety, and environmental safety.

ADR#272 - Romet for Game birds
No Western region activity on this project.

ADR#280 - Fenbendazole in Game Birds (Pheasants, bobwhite quail, partridge)
See Southern Region Report.

ADR#324 - Progesterone CIDRs for Goats (TAS, Milk Residue Study, and Efficacy)
The target animal safety study technical report has been accepted by FDA/CVM (February 2008). The milk residue study has been completed and the quality assurance inspection has been completed. The final technical report was sent to FDA/CVM in December 2008 and accepted October 2009. FDA/CVM has provided comments

regarding the efficacy protocol. The protocol has been accepted for concurrence. The efficacy study was started at UC Davis and Iowa State University during the fall of 2009.

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.

Other Projects/Activities:

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

New Projects:

Ceftiofur for Treating *Arcanobacterium pyogenes* Respiratory Infections in Deer: 17 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.

Fenbendazole for Treating Gastrointestinal Parasites in Deer: Conference call with Brent Herrig was held on September 17th , 2009. Intervet/Schering Plough has indicated interest in this label claim. Shawn Schafer from the cervid industry was contacted via e-mail on September 21st and 30th, 2009 asking if NRSP-7 could get feedback regarding the following label claim: Use of 8% fenbendazole Type A medicated article in white-tailed deer for the removal of *Strongyloides* spp., *Trichostrongylus* spp., and *Haemonchus contortus*. Still awaiting response.

Laboratory Report:

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

Usefulness of the Findings:

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

Work Planned for Remainder of the Year:

Over the next year our primary goals are to continue the CIDR-G Efficacy study, finish the analyses for the goat tulathromycin project, and finish the salmonid erythromycin environmental assessment. Submission of protocols for the florfenicol in sheep and ceftiofur for deer studies will be the focus for project development.

Manuscripts Submitted, Accepted or Published Since the Last Meeting:

Rowe, J, Tell, L, and Wagner, D. Animal safety report on intravaginal progesterone controlled internal drug releasing devices (CIDRs) in sheep and goats. J Vet Pharmacol Therap, 32(3): 303-305, 2009.

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

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

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

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

Critical Review:

1. *Work accomplished under the original project*

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

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

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

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

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

3. *Incomplete work or areas needing further investigation*

All of the projects listed above have some work that needs to be completed before they are approved by the FDA/CVM. In some cases this is just the FDA/CVM review, while in others there is work needed by the NRSP-7 project. The NRSP-7 work 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.

Southern – Dr. Alistair I. Webb

Projects in Progress

RABBITS

ADR – 0107 Ivermectin & Rabbits

The human safety and target animal safety reports are being prepared subject to completion of freezer stability. This task was treated as secondary to the fenbendazole in gamebirds but is now being pushed to completion.

BIRDS

ADR - 0280 Fenbendazole & Gamebirds

The human safety report was submitted to FDA-CVM. The concerns of UC-Davis QA resulted in (a) withdrawal of quail part of the report [QA problem with Webb's dual role as study director and QA inspector plus very problematic withdrawal conclusions]; (b) letters from site personnel were submitted to try and mitigate lack of in vivo QA inspection; (c) in vitro section QA was certified by UCD. We have just heard that the pheasant study has been rejected but we have no information of why or whether there is any possibility of re-submission. The TAS report is now complete but lacks investigator's final input and QA we are planning a 60-day completion. We are very concerned with the GLP QA aspect as it has some of the same problems as the rejected HFS submission. If critics are happy, this will be submitted to FDA within 30 days.

SMALL RUMINANTS

ADR – 0210 Fenbendazole & Red Deer & ADR – 0216 Fenbendazole & Fallow Deer.

Intervet / Schering Plough/Pfizer are still working on their combined project pipeline priorities so this project is on hold. Dose seems a critical point to be solved.

ADR - 0294 Lasalocid and Deer / ADR - 0298 Lasalocid and Goats

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

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

BEES

ADR – 0343 Remebee and Honey bees

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

Work Planned for the remainder of the Year:

- Familiarize the new coordinator with the functions of the NRSP-7 program and the souther region's role.
- Assist the new Coordinator in establishing his/her own priorities.
- Maintain lab and staff at GLP level.
- Submit by early new year all the ivermectin for rabbit reports and the TAS in gamebirds fenbendazole reports.
- Continue efforts for collaborative studies for gaining approval of fenbendazole & lasalocid in deer, and lasalocid in goats.
- Prepare, in coordination with the National Coordinator, INAD submissions for studies conducted under the aegis of the Southern Region. Initial preparation of written responses to CVM review of all of the data submitted for each project.

This is often a time consuming and unrecognized activity associated with the completion of each project and may require considerable correspondence and conversation.

- Continued collaborative work with the other regions is anticipated and may include unplanned studies to address critical needs and opportunities to collect data.
- Continue the development of the NRSP-7 web site with possible re-implementation of the RUSTi database.

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

However Dr Vickroy and I would like to have a discussion on some possible new projects:

- Flunixin in sheep & goats
- Amitraz in bees

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

OTHER BUSINESS

Future of teleconferences
Dr. Webb questioned if we want the monthly teleconferences to continue, whether they would be held on the same day same time, who will organize agenda and if CVM would continue to host them. No conclusions were reached on any of these issues, although the consensus of the group was to continue the teleconferences.

Brochure design and control
The design and control of the brochure was transferred to the National Coordinator's office.

Spring Meeting
It was decided to hold the annual spring meeting in conjunction with ARS/CSREES Public Meeting March 23-24, 2010 in Beltsville, MD. This meeting occurs every five years and allows for information sharing and priority setting for the next five years. Prior to meeting, the ARS-CSREES Animal Health team seeks input for animal disease priorities from stakeholder/partner organizations, societies and associations. USDA-Agricultural Research Service (ARS) will draft its next five-year research plan based in part on information provided. Additionally, the National Institute of Food and Agriculture will use input to help guide competitive program priorities for 2011 and beyond. It was decided that our list of stakeholders would be forwarded to NIFA to provide representatives of the minor species to the meeting.

There being no further business, the meeting was adjourned.

RESPECTFULLY SUBMITTED:
John G. Babish, Ph.D. Date: 12/22/09
NRSP-7 National Coordinator