Minutes of NRSP-7 Fall Meeting 2005
Oct 3rd & 4th, 2005

LOCATION: Fort Lee Holiday Inn, 2339 State Rt 4, Fort Lee, NJ 07024
Monday Oct 3rd 2005
NRSP-7/FDA/USDA/Alpharma
ATTENDEES: From NRSP-7, Drs. L. Garry Adams, John G. Babish, John C. Baker, David G. Thawley, Paul R. Bowser, Arthur L. Craigmill, Ronald W. Griffith, and Alistair I. Webb. USDA/CREESS representative Dr. Larry R. Miller, FDA/CVM liaison Dr. Meg Oeller and Alpharma representatives Drs James P. Peters, Mark LaVorgna, Ronald Dalrymple, James T. Skinner, Scott Wassink, and Denny Hausmann.

The National Coordinator **Dr. Babish** began the meeting by asking each attendee to give a brief introduction. The introductions were followed by an overview of NRSP-7 by Dr. John G. Babish, who then introduced **Drs. Larry Miller** and **Meg Oeller**. In brief overviews, Drs. Miller and Oeller, respectively, described the roles of USDA and FDA/CVM in the NRSP-7 program. Dr. Oeller also reviewed the recently enacted Minor Use Minor Species legislation. Regional coordinators **Drs. Art Craigmill** and **Paul Bowser** presented their work on species grouping, respectively, in avian and aquatic animals. This was followed by presentations by **Drs. Alistair I. Webb** and **Ronald Griffith** concerning research activities in their regions and potential for Alpharma projects.

ALPHARMA PRESENTATIONS

Following a short break, guests from Alpharma presented background information on the Company and interests in minor species.

James P. Peters, Ph.D., Director, Global Product Development offered an Introduction to Alpharma and Alpharma Animal Health. Dr Peters described Alpharma as a global company with 1.3 billion sales annually from human and animal drugs. Established in Norway in 1903, into the US in 1975. Their growth has been thru acquisition such as Solvay. Human drugs represent the bigger portion with most of the products being generic drugs. Alpharma is in the top ten of human generics. Their market is mainly US and Western Europe.

Animal health is about 23% of their income consisting mainly of feed additives, so no off label use of most of the products. They are currently expanding into pain management with Kadian (morphine sulfate sustained release).

Alpharma Animal Health represents $315 million in the Animal health market, out of $12 billion in the total worldwide pharma market. Of this amount 89% represents feed additives, 4% Biologicals and 7 % pharmaceuticals. Alpharma is not a discovery organization, but a delivery and marketing company. Product distribution by species includes: 53% poultry, 21% cattle, 24% swine, 2% fish. Due to an non-compete agreement with Pharmac, Alpharma is prohibited from entering the aquatic market for four years.

Dr. Mark LaVorrgna, Director of Technical Services, discussed Alpharma Technical Service and MUMS issues. This included an overview of Alpharma tech services and personnel in different states. Alpharma considers North America to be US and Canada, Mexico is included with their Latin American section. The activities of Technical Services include: (1) Market/Product support, (2) Training programs, (3) Tech support material production, (4) customer support, (5) health surveys (poultry), (6)

diagnostic evaluation (swine), (7) cattle feed mill audits, (8) new product and business development, and (9) field inquiries. Their minor species interests in this area include lasalocid in pheasants and decocox and lasalocid in deer, and elk.

Dr. Ronald Dalrymple, Director, Alpharma Global Product Regulatory Affairs described the Alpharma position on the regulatory and international prospective of the Minor Use Minor Species law. He noted that in the European Union (EU) veterinary medicines must be reregistered every five years under VICH (Veterinary International Co-operation on Harmonization - EU) guidelines. As a result, products consisting of older drugs for minor species are lost. Alpharma is currently in the process of data acquisition for minor species in the European market. Due to the loss of so many drugs, the EMEA (European Medicines Evaluation Agency) is working on a pilot system to help out with the MUMs drugs. MRL (Maximum Residue Limit) extrapolation for minor species is also undergoing reconsideration. In the EU, feed additives go thru a different agency than the CVMP (Committee for Medicinal Products for Veterinary Use), there is a separate Feed Additives agency, and there are drugs just for use in single countries. It is possible to market a drug specifically in just one country. Most new products go thru the CVMP for all the countries.

In Europe and Asia the definition of a minor species it is even more confusing than in the US. Alpharma is considering a MUMs program spanning 1.5 to 5 years for turkey, sheep, rabbit, ducks and game bird drugs. In Asia ducks and fish are major species. The major export country for Asia is the EU and so Asian producers watch approved drugs there and are trying to be careful with their uses. Many Alpharma products are used off label in Asia. In Canada, the vets can script feed meds legally. Dr. Dairymple concluded that a real harmonization of requirements would greatly assist the development of products for minor species in the US.

James T. Skinner, Ph.D., Leader, Alternative Additives related the topic of Current Uses of Alpharma products for MUMS. In his presentation, Dr. Skinner noted a partial listing of the Alpharma minor species claims:

Rofenaid, avatek: chukar, Rofenaid 40: ducks and chukars, Albac50: pheasants, Baciferm: growing quail, Aureomycin, Chlortet: ducks, exotics (cockatoo, macaws, psitticine birds) and sheep (growing), Avatec, Bovatec (lasalocid): avateck for chukar, bovatec for sheep and rabbits, BMD (bacitracin): pheasant, quail, Deccox: sheep and goats, and NeoSol: goats and sheep. In conclusion, Dr Skinner noted that Alpharma was interested in deer and elk in the US and queried as to how Alpharma and NRSP-7 might work together.

The topic of markets needs and sizes for deer and elk was outlined by **Mr. Scott Wassink**, National Accounts Manager – Livestock. His opening statement offered that Purina brand is really very interested in this market as they feed more game animals than anyone else in the US. In order of size, the three target groups in this market include native deer, elk and exotic game. Deer are the largest group consisting of approximately 25 million whitetail and 3 to 4 million mule deer.

In the US, Texas with 1.5 million farming acres and 50 million acres leased for hunting has the most high-fence deer area. In South Dakota, they also offer land for hunting.

All captive deer are fed rations. Mortality is about 10-15% per year, mostly bucks after rut (injuries, stress) 80% mortality right after the rut, primarily due to pneumonia, coccidian foot rot, and poor condition. An estimated 0.25 million deer are in breeding captive operations. Two super bucks have been cloned and it appears that cloning of

trophy deer is here to stay. Drug needs for deer include Chlortet for rut and Bovatec and Deccox for coccidiosis.

There are 750 elk breeding operations in the US. These are concentrated in the Midwest and Colorado. Elk represent a very fast growing feed market with about 60,000 captive and 600,000 native elk in the US. At Alpharma Interest is very high on developing products for elk husbandry. Feed supplementation is rare as elk are migratory. Mature bulls will bring $2,500-10,000.

Approximately 250,000 antelope are raised commercially in the US. The males are sold into hunting and females are used for breeding. Farms characteristically are free-range operations with high fencing. Most are fed supplemental rations. Drug needs in this market include Bovatex and Chlortet for respiratory diseases, Deccox and AS-700, a chlortetracycline-sulfa combination.

Finally, the topic of product needs and gaps for sheep and goats was presented by Mr. Scott Wassink and **Dr. Denny Hausmann**, DVM, Manager, Technical Services – Cattle. Following a review of statistics on sheep and goat farms in the US, the needs of sheep and goat farmers were summarized as drugs for the treatment of foot rot and pinkeye.

During the remainder of the day, there was a discussion of current and future Alpharma projects and how each could be benefited as an NRSP-7 project. The meeting concluded at 3:45 pm.

Tuesday Oct 3rd, 2005

LOCATION: Fort Lee Holiday Inn, Fort Lee, NJ 07024, Martha Washington Conference Room

ATTENDEES: Drs. L. Garry Adams, John G. Babish, John C. Baker, David G. Thawley, Paul R. Bowser, Arthur L. Craigmill, Ronald W. Griffith, and Alistair I. Webb. USDA/CREESS representative Dr. Larry R. Miller, FDA/CVM liaison Dr. Meg Oeller

ADMINISTRATIVE REPORTS

REPORT FROM THE ADMINISTRATIVE ADVISORS

Dr. L. Garry Adams, chair of the Administrative Advisors, presented the report. He began by reviewing the meeting of the previous day with Alpharma. It was agreed by all attendees that Alpharma demonstrated a strong interest in the NRSP-7 program by the quality and breath of the presentations by the regional coordinators, maintaining INADs, and the process of selecting replacements for regional coordinators.

REPORT FROM USDA-CSREES

Dr. Larry Miller informed Regional Coordinators about the upcoming grant period and requested that each be prepared for submitting renewals this January. Dr. Miller also distributed handouts with project termination dates and discussed each project nearing termination.

REPORT FROM CVM

Dr. Meg Oeller reviewed current activities at CVM for each active project. It was decided that Regional Coordinators would submit their semi-annual reports to her as well as to the National Coordinator. Dr. Oeller agreed that this would help her maintain the active projects listing at CVM by providing updates on any activity in a particular project.

REPORT FROM THE NATIONAL COORDINATOR

Dr. John G. Babish reported on his attendance at the meetings of the Western and North Central Experiment Station Directors.

REPORTS FROM THE REGIONAL COORDINATORS

Northeastern Region - **Dr. Paul Bowser**

PROGRESS OF THE WORK AND PRINCIPAL ACCOMPLISHMENTS

Hydrogen Peroxide Project:

ADR 259 Hydrogen Peroxide as a Therapeutic Compound for Bacterial Gill Disease in Fish. (INAD 9493)

During this reporting period one manuscript has been submitted for publication. 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

A primary constraint in the availability of therapeutic compounds for the Aquaculture Community is the relatively large number of fish species that are currently cultured or that have significant potential as commercial species. Currently, research in support of a label for a therapeutic compound must be performed separately for each species for which the label is desired. We have undertaken a project designed to show the similarities in how drugs are handled by different fish species with the goal of supporting a species (crop) grouping concept for fish. We have conducted these studies in a collaborative effort with the Western Region NRSP7. Within this context, to date we have completed the following preliminary Human Food Safety/Tissue Depletion Studies using the following test articles as model compounds:

Oxytetracycline:

1. Walleyes, freshwater fish, 15C and 20C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass, saltwater fish, 20C and 25C
4. Summer Flounder, saltwater fish, 17C and 20C

Romet-30:

1. Walleyes, freshwater fish, 20C and 25C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass (would not accept the ration; see below)
4. Summer Flounder, saltwater fish, 17C and 20

Florfenicol:

1. Walleyes, freshwater fish, 20C and 25C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass, saltwater, 20C

Data from these species will be compared to data currently available for the cold water species, rainbow trout (freshwater) and Atlantic salmon (marine). Data from studies of Oxytetracycline in the four

species indicated above has been published in several peer-reviewed manuscripts.

In addition to the species grouping effort with Oxytetracycline, we completed one cold water temperature Human Food Safety/Tissue Depletion Study in rainbow trout. This study was completed at the request of CVM/FDA. The study involved medicating market size rainbow trout and following elimination of the test article in the edible portion of the fish (filet with skin on, but descaled). The study was conducted at 8C. Oxytetracycline concentration in the edible portion never exceeded the 2.0 mg/Kg action level at any time during the study.

Several attempts were made to conduct human food safety studies or Romet-30 in hybrid striped bass. Although extremely active feeding on a non-medicated ration was observed during acclimation, the hybrid striped bass refused to consume the Romet-medicated ration on all attempts to initiate a trial. As a result, hybrid striped bass were eliminated from our testing matrix for Romet-30. The Sponsor has reported that they have developed a product that circumvents the palatability problem and we anticipate efforts to complete the Human Food Safety/Tissue Elimination studies in that species.

More recently, we have completed Human Food Safety/Tissue Depletion Studies using Aquaflor (Florfenicol, Schering-Plough) as a model compound, with studies completed in walleyes (20C, 25C), tilapia (25C, 30C) and hybrid striped bass (20C). These studies were conducted with a dose of 10 mg drug/kg fish/day for 10 days. We anticipate the conduct the trial with hybrid striped bass at 25C in the near future.

In a related effort requested by the sponsor (Schering-Plough), we have evaluated the question of fish size using our standard testing protocol for Human Food Safety/Tissue Elimination studies. This study was also conducted in light of the recent communication with the sponsor that they anticipate a label dose of 15 mg drug/Kg fish/day for 10 days for the treatment of Streptococcus infection in tilapia. The in-life portion of the Tilapia size studies have been completed:

1. Tilapia, freshwater fish, 25C, 15 mg/Kg, 10d 100gm
2. Tilapia, freshwater fish, 25C, 15 mg/Kg, 10d 250gm
3. Tilapia, freshwater fish, 25C, 15 mg/Kg, 10d 500gm

Samples from these studies are being analyzed in a cooperative effort with the Western Region NRSP7.

INAD 10-804 Rofenaid in Pheasants

A Target Animal Safety of Rofenaid in pheasants as well as an efficacy trial of Rofenaid for treatment of Pasteurella multocida. Reports on these trials are being prepared.

ADR 259 Hydrogen Peroxide as a Therapeutic Compound for Bacterial
Gill Disease in Fish. (INAD 9493)
No additional work is planned for this project in the upcoming year.

USEFULNESS OF THE FINDINGS

In all cases, the findings 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.

PRINCIPAL PUBLICATIONS (DURING THIS YEAR):

Chen, C.-Y., G.A.Wooster, and P.R.Bowser. 2004. Comparative blood chemistry and histopathology of tilapia infected with Vibrio vulnificus or Streptococcus iniae or exposed to carbon tetrachloride, gentamicin, or copper sulfate. Aquaculture 239:421-443.

Chen, C.-Y., R.G.Getchell, G.A.Wooster, A.L. Craigmill and P.R. Bowser. 2004. Oxytetracycline residues in four species of fish after 10-day oral dosing in feed. Journal of Aquatic Animal Health 16:208-219.

Wooster, G.A. C.M. Martinez, D.S. Ohara, and P.R. Bowser. 2005. Human Health Risks Associated with Formalin Treatments Used in Aquaculture: Initial Study. North American Journal of Aquaculture 67:111-113.

Chen, C.-Y. and P.R. Bowser. 2005. Pharmacokinetics of oxytetracycline in Nile tilapia (Oreochromis niloticus)challenged with Streptococcus iniae and Vibrio vulnificus. Journal of the World Aquaculture Society 36:262-270.

Chen, C.-Y., G.A. Wooster, R.G. Getchell and P.R. Bowser. 2005. Distribution and depletion of oxytetracycline in two warm-water fish: tilapia and hybrid striped bass. Journal of the World Aquaculture Society 36:in press.

Tort, M.J., D. Hurley, C. Fernandez-Cobas, G.A. Wooster and P.R. Bowser. 2005. Effects of hydrogen peroxide treatments on catalase and glutathione activity in walleye (*Sander vitreus*). Journal of the World Aquaculture Society 36:in press.

Chen, C.-Y., C.-B. Chao and P.R. Bowser. 2006. Infection of tilapia Oreochromis sp. by Vibrio vulnificus in freshwater and low salinity environments. Journal of the World Aquaculture Society. 37(1): in press.

ABSTRACTS

Kosoff, R.E., G. Wooster, R. Getchell, and P. Bowser. 2005. Residue depletion of Aquaflor compared in walleye and tilapia.
2005 Annual Meeting of the Fish Health Section/American Fisheries Society. Minneapolis, MN. 26-29 July 2005.

Kosoff, R.E. and P.R. Bowser. 2005. Effects of Florfenicol on CYP1A Expression and activity in Tilapia (Oreochromis niloticus).
2005 Annual Meeting of the Fish Health Section/American Fisheries Society. Minneapolis, MN. 26-29 July 2005.

Bowser, P.R. 2005. NRSP7 Minor Use Animal Drug Program - Species Grouping for Aquaculture. 11th Annual FWS Drug Approval Coordination Workshop. 2-3 August 2005. Bozeman, MT.

Southern Region – **Dr. Alistair I. Web**

PROGRESS OF THE WORK AND PRINCIPAL ACCOMPLISHMENTS

The GLP inspection of our chemical assay section by the Western Region has been completed and all issues addressed satisfactorily.

RABBITS

ADR – 107 IVERMECTIN & RABBITS

The assay has been validated and the in vivo depletion stage is about to start. The assay is being bridged with beef [species the residue method was developed in]. Ms Ogletree Davis will return to inspect the *in vivo* stage in November.

FISH

ADR - 271 CRUDE CARP PITUITARY

The TAS report is still with FDA. No news on any potential manufacturer.

BIRDS

ADR - 280 FENBENDAZOLE & GAMEBIRDS

I have broken my self-imposed timetable and the TAS report failed to meet the fall submission but will be done in the next 60 days. We are waiting for Western Region's depletion assay results and it is hoped that there will be a fast turn round in submitting that to CVM.

DEER

ADR – 210 FENBENDAZOLE & RED DEER & ADR – 216 FENBENDAZOLE & FALLOW

We are waiting to have a teleconference with CVM and Intervet to spell out requirements and then we can submit a budget. Plan at the moment is that NRSP-7 will do the TAS and human safety and the efficacy, conducted by Intervet, will follow – risk there is if the effective dose is higher that that used in the two former studies' they would have to be repeated. The investigator for the TAS and human safety work has been identified [UF Zoo Vet – Ramiro Isaza] and Dr. Bermingham is our contact and infers they [Intervet] have $ to help with the project. We are trying to get FDA to define what species we need to get a deer label.

ADR - 294 LASALOCID AND DEER / ADR - 298 LASALOCID AND GOATS

A teleconference is planned for November 18th which will allow us to define requirements and develop budgets. Like the FBZ project, Alpharma will do the efficacy after the TAS and Human safety with the same risks involved. We have investigators lined up for both deer and goat work at UF.

Western – **Dr. Arthur L. Craigmill**

PROGRESS OF THE WORK AND PRINCIPAL ACCOMPLISHMENTS

ADR#325 - Florfenicol for sheep for respiratory disease.

The MIC technical report is complete and under review by SPAH. The human food safety portion is under QA review in house. Both reports should be submitted before the end of the year.

ADR#324 - Progesterone CIDRs for Goats

A product development conference call was conducted on August 23 and agreement reached on what needed to be in the protocols for efficacy, target animal safety and human food safety. The TAS study began on September 7, 2005.

ADR#311 - Lincomycin for Bees
Data accepted by CVM and Public Master File published.

ADR#272 - Romet for Gamebirds
See species grouping report.

ADR#299 - Pirlimycin for Dairy Goats
No progress since last meeting.

ADR#295 - Strontium Chloride for Salmonids. Steve Schroeder
Nothing to report from the region.

Collaborative Projects:
ADR#280 - Fenbendazole in game birds (Pheasants, bobwhite quail, partridge)
See Southern Region report.
Species Grouping Fish:
Samples currently undergoing analysis for florfenicol, see Dr. Bowser's report, in our laboratory so far this year, for the fish species grouping project we have analyzed 38 feed samples, 390 plasma samples and 219 muscle samples. WR Laboratory personnel are currently working on muscle samples from trial 2004-5, and 2005-3.

PRINCIPAL PUBLICATIONS (DURING THIS YEAR):
Cortright, K.A. and Craigmill, A.L. In Vitro and In Vivo Kinetics of Midazolam in Commercially Raised Gamebirds (Abstract) 44th Annual Meeting of the Society of Toxicology, #1561, 2005.

North Central – **Dr. Ronald W. Griffith**

PROGRESS OF THE WORK AND PRINCIPAL ACCOMPLISHMENTS

CIDRg in Ewes

Dr. Dennis Hallford at New Mexico State University has completed the tissue residue analysis for progesterone and has submitted the data to the FDA/CVM for review. The reviewers had some questions concerning the method validation submitted earlier and Dr. Hallford has responded to those questions.

Florfenicol (Aquaflor) in shrimp

Dr. Delbert Harris has submitted one publication and one poster covering his work with Necrotizing Hepatopancreatitis in shrimp. Infected and uninfected shrimp were treated with Aquaflor at 0, 167, 333 and 667 mg/kg of pelleted ration. By 43 days post infection, the treated groups had suffered 60% mortality. There was slight evidence of some toxicity at the 667 mg/kg dose. In addition, Dr. Harris reported that the Aquaflor was leaching out of the pellets and about 50% of the active drug leached out. Also, reports from Mexican shrimp growers indicate a similar problem and relatively low efficacy of Aquaflor against NHP. Dr. Craigmill has requested that we send him some of the treated shrimp to assay their tissues for florfenicol.

CIDRg in Goats

A product development telephone conference for CIDR's in goats was held in August. The North Central region will be working with Dennis Hallford to duplicate the sheep tissue residue work in goats. The Western Region will handle TAS and Efficacy. The in-life phase of the milk residue studies will either be done in the North Central Region (if a suitable local herd of milking goats can be found) or Western Region with the UC Davis herd. The analysis phase will be performed by Dr. Hallford.

Lasalocid in pheasants

We are waiting on information from the manufacturer outlining what has been done in Europe with the approval of Lasalocid in gamebirds. Efficacy data generated in Europe may need to be repeated in the U.S. but other components of the approval package may be acceptable to CVM. Subsequent to receiving information from the manufacturer, we should be able to hold a product development conference and decide what needs to be done in the U.S. to support product approval of Lasalocid as a coccidiostat in pheasants.

NEW PROJECT PROPOSALS OR WORK FOR NEXT YEAR

Northeastern – **Dr. Paul Bowser**

Species Grouping Project:

INAD 10-320 Oxytetracycline in Fish

INAD 10-823 Romet-30 in Fish

INAD 11-145 Aquaflor (Florfenicol) in Fish

The conduct of Efficacy and Target Animal Safety Studies are anticipated in the coming year. These efforts will focus on efficacy of the compounds on bacterial pathogens of fish, particularly those of cool water species such as percids (e.g. walleye, yellow perch) and esocids (e.g. northern pike, muskellunge). These studies will be initiated when diagnosed field cases can be identified that will lend themselves to the implementation of controlled field studies. It is likely that these studies will be conducted in the fish hatchery system of the New York State Department of Environmental Conservation.

We have recently initiated efforts to include the compound Aquaflor (Florfenicol, Schering-Plough) within our species grouping effort for fish. Our initial efforts with Aquaflor have been in the area of Human Food Safety/Tissue Elimination. To date trials with tilapia (25C, 30C), walleyes (20C, 25C) and hybrid striped bass (20C) have been completed. We plan to conduct trials in hybrid striped bass (25C) in the near future. We have recently completed the in-life phase of studies in tilapia designed to document depletion kinetics of Aquaflor (25C, 15 mg/kg/day for 10 days) in fish of different sizes (500g, 250g, 100g). Tissues from these studies are currently being analyzed.

Rofenaid in Pheasants INAD 10-804

We are considering the conduct of an efficacy trial of Rofenaid for the treatment of coccidia in pheasants. A literature search is being conducted to determine if there is an organism that will be suitable for a model challenge study.

Minor Species Efforts in Goats

Preliminary efforts are underway to establish a minor species project in the Northeast Region that will focus on needs of the goat industry. This effort will be under the leadership of Dr. Mary Smith, Department of Clinical Sciences, College of Veterinary

Medicine, Cornell University. Specific details of this study are still in the developmental stages.

Southern – **Dr. Alistair I. Webb**

POTENTIAL NEW PROJECTS

Fasinex® in deer. Trichlorbendazole is a drug that Novartis has approved for sheep, cattle and deer in Europe. It is especially being requested for red and fallow deer which are unnatural hosts for Fascioloides and it is frequently fatal. Novartis have perked up on this but say their tox package is old and may have a rough passage through FDA. The lure of MUMS and possibility of major species extension later may get them to play. Lee Whaley is our contact at Novartis. No news on this – will try and see if they really are interested and get an ADR submitted

Ovaprim [ADR 335] and metomidate [ADR 336]. I would like to discuss these two ADRs. Ovaprim is requested as a spawning aid in ornamental fish and metomidate for sedation during transport. Dr. Yanong and Syndel are the requesters and have / had a private INAD. We had a teleconference with CVM. The Southern Region has been providing GLP training and it is proposed we provide QA/QC for the Ruskin laboratory

CONTINUED WORK

1. Maintain lab and staff at GLP level
2. Submit by year's end the ivermectin for rabbit TAS and all fenbendazole reports, and repeat the *in vivo* ivermectin depletion study.
3. Revive, plan, initiate and organize studies for gaining approval of fenbendazole & lasalocid in deer, and lasalocid in goats.
4. 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.
5. Continued collaborative work with the other regions is anticipated and may include unplanned studies to address critical needs and opportunities to collect data.
6. Continue the development of the NRSP-7 web site with full activation of the RUSTi database.
7. Web site - The NRSP-7.org web has completed the move to a new server. This was not smooth as switching to new server software was fraught with several crashes – no data lost but programmer had to be talked in off the window ledge. The problems were exacerbated by our migration to semi-control by CVM IT but in the long run we got excellent backup and technical assistance. The MUMSRx web database continues to be updated – it alone receives 1-2 hits each day. Rusti is now fully functional so I will be working with each coordinator to get active projects fully entered into the system. I may have some delays as our biological scientist will be taking Family Medical Leave next spring. Question: should we look at getting Meg trained in the system.

Western – **Dr. Arthur L. Craigmill**

POTENTIAL NEW PROJECTS:

Intramammary ceftiofur: no progress to report.

CONTINUED WORK

Krsity Cortright has almost finished her work on the *in vitro* studies, there are just a couple more runs to be made to finish this section. We have submitted a paper on the first portion of the *in vitro* modeling to JVPT. The PBPK model for the birds will be accomplished during the summer of 2006. Whole animal studies have been run in all species for serum pharmacokinetics of midazolam, the CYP3 marker substrate. Tissue analysis will take much longer to complete so that we can validate the PBPK model with the inclusion of the *in vitro* data. We are looking for a rapid LC-MS assay to facilitate the tissue analysis, and hope to complete this project by the fall of 2006.

The completion of the projects previously discussed is the primary work planned for next year. We will continue with the species grouping work, finish all the florfenicol tissue residue analysis, prepare the reports, and begin protocol preparation for the OTC in abalone. CIDR work will be extended to goats, and we hope to be able to plan a residue study of ceftiofur in lactating dairy goats and possibly sheep, Pfizer willing.

North Central – **Dr. Ronald W. Griffith**

POTENTIAL NEW PROJECTS

Regulin (melatonin) and Fecundin

Regulin (melatonin) is approved for use in Australia as an aid for out-of-season breeding and increasing conception rates in ewes. A request to investigate the possibility of working toward approval of this drug was received from Dan Morrical at Iowa State University. Melatonin is given as an implant in the ear for sustained release. Dr. Morrical also expressed an interest in an approval for Fecundin which induces an auto-immune response against LH.

CONTINUED WORK

The completion of the projects previously discussed is the primary work planned for next year.

SPRING MEETING

A vote on the date of the Spring meeting provided at tentative date of May $11^{th}/12^{th}$ in Rockville, MD . It was also decided to invite stakeholders representing the Deer Industry and Animal Health Institute. The National Coordinator, with assistance from Regional Coordinators will identify appropriate individuals from each of the two stakeholder groups and see to it that they are invited for a presentation.

OTHER BUSINESS

There being no other business, the meeting was adjourned

Respectfully submitted:

John G. Babish, Ph.D. Date: 12/6/05
NRSP-7 National Coordinator