Minutes of NRSP-7 Annual Fall Meeting 2008
September 25th & 26th, 2008

Date: September 25th, 2008

ATTENDEES: The NRSP-7 technical committee, which is made up of a National Coordinator, four Regional Coordinators, four regional Administrative Advisors, and liaisons from USDA and FDA. In attendance were the National Coordinator, Dr. John Babish (Cornell University), the Regional Coordinators, 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), Administrative Advisors Dr. Garry Adams, Chairman of Administrative Advisors (Texas A&M) and Dr. John Baker (Michigan State University), and the FDA liaison Dr. Meg Oeller (Rockville, MD).

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LOCATION:
8:30 am – 10:30 am
NRSP-7 tour of Metzer Farms Duck and Goose Game Bird Hatchery (http://www.metzerfarms.com/)
Metzer Farms
26000 Old Stage Road,
Gonzales, CA 93926

The NRSP-7 group was hosted for a tour of **Metzer Farms Duck and Goose Game Bird Hatchery.** During the tour, the farm supervisors emphasized the use of unique husbandry techniques, vaccines and facility architecture to minimize disease outbreaks. The also underscored the need, however, for more therapeutics to address those times when it is necessary to treat sick animals and prevent the spread of infection to other birds.

2:00 – 5:00 pm
Monterey Aquarium Tour (http://www.montereybayaquarium.org/)
886 Cannery Row
Monterey, CA 93940

Dr. Mike Murray led the NRSP-7 group through a tour of the Monterey Aquarium. During the tour, Dr. Murray underscored the unique husbandry techniques employed at the aquarium and specific therapeutic needs of the species exhibited at the aquarium.

Date: September 26th, 2008

LOCATION: Embassay Suites Hammons Boardroom, Seaside, CA 93955

PARTICIPANTS:

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REPORTS FROM THE REGIONS AND NEW PROJECTS:

NORTHEASTERN REGION - **DR. PAUL BOWSER**

Progress of the work and principal accomplishments:

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

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
5. Rainbow Trout, cold water trial (8C)

Romet-30:

1. Walleyes, freshwater fish, 20C and 25C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass (to be completed;see below)
4. Summer Flounder, saltwater fish, 17C and 20C

Florfenicol (10 mg/Kg/d, 10d):

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

Florfenicol (Effect of fish size)

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

25C, 15 mg/Kg, 10d

3. Tilapia – 500 gm, freshwater fish,
   25C, 15 mg/Kg, 10d

Several attempts were made to conduct human food safety studies for Romet-30 in hybrid striped bass. These attempts were unsuccessful due to lack of feed acceptance by the fish due to apparent palatability problems. Since that time, the Sponsor had developed and marketed a product (Romet-TC) designed to circumvent palatability problems. In two attempts with this new product, we found that hybrid striped bass would not accept a ration medicated with Romet-TC. Therefore, we will not include hybrid striped bass in our efforts with Romet.

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 (Florfeniol) in trout, salmon and catfish.

Work planned for next year:

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.

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 conducting 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.

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.

Target animal safety studies have been completed in both rainbow trout and walleye. Information collected during these studies constituted the subject of eight manuscripts in the peer-reviewed literature and several presentations at scientific meetings. Our raw data and a peer reviewed publication (see Saez and Bowser 2000 below) describing discharge kinetics of hydrogen peroxide from a fish hatchery were provided to the U.S. Geological Survey Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin, for their use in the recent submission that resulted in a label for hydrogen peroxide. We also provided reprints of our eight

peer reviewed publications to the Sponsor in response to their request as they prepared their "all other relevant information" submission.

(B) Species Grouping in Fish

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

Our efforts have focused on evaluation of a species grouping concept for finfish. Within this effort we have conducted Human Food Safety/Tissue Elimination Studies as follows:

Oxytetracycline
- Tilapia (25C, 30C) - completed
- Walleye (15C, 20C) - completed
- Hybrid Striped Bass (20C, 25C) - completed
- Summer Flounder (17C, 20C) – completed

Results of studies conducted in the above four fish species are summarized in the publication:

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.

- Rainbow Trout, cold water trial (8C) - completed

Romet-30
- Tilapia (25C, 30C) - completed
- Walleye (20C, 25C) – completed
- Summer Flounder (17C, 20C) – completed

Results of studies conducted in the above three fish species are summarized in the publication: Kosoff, R.E., C.-Y. Chen, G.A. Wooster, R.G. Getchell, A.Clifford, A.L. Craigmill and P.R. Bowser. 2007. Sulfadimethoxine and Ormetoprim Residues in Three Species of Fish After 5-day Oral Dosing in Feed. Journal of Aquatic Animal Health 19:109-115

Hybrid Striped Bass (20C, 25C) - did not accept feed medicated with Romet-30; palatability problems; two additional trials were attempted with feed medicated with Romet-TC (a product developed to avoid palatability problems). These additional studies were also unsuccessful because of lack of feed acceptance due to apparent palatability problems by the hybrid striped bass. No further work with Romet-30 or Romet-TC is currently planned.

Aquaflor (10 mg/Kg/d X 10 days) Tilapia (25C, 30C) - completed
- Walleye (20C, 25C) - completed
- Hybrid Striped Bass (20C, 25C) - completed

Aquaflor (15 mg/Kg/d X 10 days)
- Tilapia
  - 100 gm fish - completed
  - 250 gm fish - completed
  - 500 gm fish - completed

Results of studies conducted with Aquaflor are summarized in the following two publications that are currently in review:

Kosoff, R.E., C.-Y. Chen, G.A. Wooster, R.G. Getchell, A. Clifford, J.L. Craig, P. Lim, S.E. Wetzlich, A.L. Craigmill, L.A. Tell and P.R. Bowser. 2008. Florfenicol Residues in Three Species of Fish After10-day Oral Dosing in Feed. Journal of Aquatic Animal Health. In press

Bowser, P.R., R.E. Kosoff, C.-Y. Chen, G.A. Wooster, R.G. Getchell, J.L. Craig, P. Lim, S.E. Wetzlich, A.L. Craigmill, and L.A. Tell. 2008. Florfenicol Residues in Nile Tilapia After 10-day Oral Dosing in Feed: Effect of Fish Size. Journal of Aquatic Animal Health. In press

Our protocol employed the optimum culture temperature for each fish species, plus one additional lower temperature at which the species might be cultured in an economically viable manner. A preliminary evaluation of our data suggests that Oxytetracycline and Romet-30 were eliminated from the edible portion of the fish at rates that will very likely be within the current label for salmonids and channel catfish.

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 finfish will be a major undertaking in the upcoming years.

NORTH CENTRAL REGION - **DR. RONALD W. Griffith**

SHEEP CIDR-G

Sheep CIDR-g Tissue Residue Stability

This study was performed by Dr. Dennis Hallford at New Mexico State University in cooperation with both the Western and North Central Regions. The study report was not accepted due to the instability of progesterone in fresh liver tissues such that freezer stability could not be documented. ONADE is currently trying to demonstrate by reference that plasma progesterone levels decrease dramatically once the CIDR-G inserts are removed and use this to infer that overall tissue residues are markedly reduced. Muscle tissue progesterone levels were demonstrated to be at normal background levels 24 hr. after CIDR removal

GOAT CIDR-G

Goat CIDR-g Milk Residue

These studies are being supported by both the NC and Western Regions of NRSP-7. The in-life phase of milk residue study was performed at UC-Davis in fall 2007 and the analytical phase was performed by Dr. Hallford at New Mexico State University. The data from the study has been submitted for QA to the Western Region and the study report should be submitted shortly. The data indicate that progesterone levels in the milk of pregnant does are greater than progesterone levels in the milk of CIDR-treated does. Dr. Hallford plans on performing the tissue residue portion of the study this fall but wanted to wait for resolution of the sheep tissue residue

issues. I have encouraged him to submit the goat protocol so that we can get it reviewed in time to begin the study.

Goat CIDR-g Tissue Residue

Currently planned for Fall 2009. Dennis Hallford plans to perform both the in-life phase and residue analysis.

Goat CIDR-g Effectiveness

Re-revision of the protocol is underway. Hopefully study will begin in late summer/fall 2009.

TULATHROMYCIN

Draxxin Target Animal Safety in Goats

The in-life phases of the study were completed on March 22, 2008. The tissues from the untreated control and high-dose-group goats were examined for histopathology. Some minor lesions were observed in both groups and it was decided to examine the tissues from the 1X and 3X groups just in case ONADE would want that data. All the goats remained in good health except for one untreated control goat that developed respiratory disease. A few of the goats had some scattered gross lesions that seemed to be related to infectious processes rather than any toxic effects of the drug. In addition to the TAS portion of the study, we collected tissues and plasma for tulathromycin analysis for publication purposes.

Draxxin Efficacy in Goats

The protocol for a natural exposure model has been accepted by CVM. However, the studies were predicted to take at least three years to complete and require a significant portion of the financial resources of the NC Region. An alternative protocol based upon determination of AUC/MIC was prepared and submitted. However, ONADE wanted us to base statistical significance by comparison to cattle AUC/MIC. We were asked to provide an alternative target for determining effectiveness. It was decided that we needed some preliminary analytical and MIC data in order to set a realistic target. We have procured and tested a small group of bacterial isolates for MIC's. The MIC's are very close to those described for cattle. Plasma samples were collected from 6 goats and these have been analyzed for tulathromycin levels.

Draxxin Tissue Residue

The protocol has been reviewed by ONADE and there were relatively few comments. The protocol was amended and sent to Scott Wetzlich who will be doing the analysis. The methods for tissue extraction and tulathromycin analysis is currently being developed. This study can begin whenever the assays are validated. We will have tissues from goats at 2-, 3-, 4- and 5-weeks post treatment for determination of a target end point for the tissue residue study.

LASALOCID

Lasalocid Efficacy in Pheasants

The study was performed by Drs. Larry McDougald and Lorraine Fuller at the University of Georgia with the assistance of Dr. Thomas McQuistion from Milliken University. A draft of the final report and an associated paper for publication was received on April 16, 2008. The full study report has been requested several times.

Lasalocid TAS in Pheasants

The protocol for this study was submitted to ONADE for review and was returned in early July. Drs. McDougald and Fuller have agreed to perform this study as well.

Lasalocid Human Food Safety in Pheasants

This project was traded to the Western Region in exchange for the CIDR-G goat effectiveness study.

MELATONIN

Regulin (melatonin) implants for sheep

No activity to report. There does not seem to be much interest in this product either from the manufacturer or the sheep and goat industry.

EPIDERMAL GROWTH FACTOR

Bioclip for Sheep

No activity to report.

TRICLABENDAZOLE

Fasinex (Triclabendazole) for Deer and Elk

No Activity to report.

SOUTHERN REGION – **DR. ALISTAIR I. WEB**

Projects in Progress:

RABBITS

ADR – 0107 Ivermectin & Rabbits

The human safety and target animal safety reports are being prepared. This task is being treated as secondary to the fenbendazole in gamebirds.

FISH

ADR - 0271 Crude Carp Pituitary

The project appears dead from FDA/CVM's perspective. Query change RUSTi status to dead?

BIRDS

ADR - 0280 Fenbendazole & Gamebirds

The human safety report has been re-vamped and been brought to this meeting for UC-Davis QA The TAS report continues to be incomplete but lacks investigator's final input and QA we are [planning a 90 day completion. . If critics are happy, this will be submitted to FDA within 45 days.

DEER

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

Intervet have indicated that they want to carry out a dose study before moving on this project. This is with Don Davis at TAMU. The Intervet merger has given all involved brain freeze.

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

A Problem is that Alpharma will only proceed if there is a zero withdrawal time. We are well into validating an assay and will carry out initial pilots on two deer and two goats to see if the lasalocid levels are below tolerance. See below for TAMU collaboration.

The assay method has been finalized and validation starting for pheasants, goats and deer. The time table for that will be discussed at the meeting.

BEES

ADR – 0343 Remebee and Honey bees

This is a project that is in development with Beeologics for a Israel Acute Paralysis Virus [IAPV] specific double strand RNA product for prevention of collapsing colony disorder. The company has obtained an INAD and is setting up a teleconference with FDA/CVM next month after which NRSP-7's role may become clear. UFL has signed a non-disclosure agreement with Beeologics covering Remebee. It's status in RUSTi is pending.

Work Planned for the remainder of the Year:

- Maintain lab and staff at GLP level
- Submit by the new year the all ivermectin for rabbit reports and all fenbendazole reports.
- Organize 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:

With no assured funding in sight, no new projects are under consideration with primary effort being made to complete existing studies and we are trying to collaborate with TAMU to start work on lasalocid deer & goat projects.

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 on the current coordinator's retirement in May 2010.

Coordinator Retirement

It appears that UFL and TAMU have groups interested in this despite some reservations about funding.

WESTERN – **DR. LISA TELL**

ACTIVE REGIONAL PROJECTS:

Progress of Work and Principal Accomplishments:

ACTIVE Regional Projects:

ADR#325 - Florfenicol for sheep for respiratory disease

Schering-Plough has been contacted and is interested in pursuing a bioequivalence study for the sheep using the new formulation. We are currently waiting for a response from Dr. Oeller regarding setting up a conference call with the investigators, manufacturer and CVM.

ADR#324 - Progesterone CIDRs for Goats (TAS and Milk Residue Study)

Target Animal Safety report has been accepted by FDA/CVM (February 20, 2008). Milk residue study has been completed. Raw data for goat milk progesterone concentrations have been sent to UC Davis by Dr. Dennis Hallford from New Mexico State University. The QA of Dr. Hallford's data has been completed. The final report submitted by Drs. Rowe and Hallford is now undergoing QA review. This report will be sent to FDA/CVM in October 2008.

ADR# 235 - Lasalocid in Ring-Necked Pheasants (Human Food Safety/Residue Study)

The general protocol has been written except for the final details regarding the analytical methods and formulation of the premixed medicated feed. A study director has been identified

from UC Davis' Center for Laboratory Science. A location for mixing the feed has been identified. The UC Davis animal care and use protocol has been submitted. The protocol will be submitted to CVM for concurrence in October or November.

ADR#272 - **Romet for Gamebirds**

See species grouping report.

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

Mark Gaikowski with the U.S. Geological Survey (Upper Midwest Environmental Sciences Center in La Crosse, Wisconsin) is working in conjunction with NRSP-7 to revise and review specific sections of the Environmental Assessment Report for resubmission to CVM. In order to address the CVM comments, a pilot chronic toxicity study with *Daphnia magna*, is currently underway, using erythromycin thiocyanate (ERTT) and diphenhydramine (DERT). The report for this study is being finalized and should be completed soon. The no observed effect concentration (NOEC) developed from this study was similar to the data from the *Ceriodaphnia* study included in the environmental assessment (EA). The USGS is also planning to complete a follow-up ERTT study this fall with *Daphnia* to supplement the initial work. Another study on ERTT physical chemistry has been completed and the transformation kinetic sample results should be processed by October 1 with a draft manuscript done in December. This manuscript will be revised into a final report to include with the EA. The ultimate goal of these studies is to produce data that will address CVM's concerns regarding chronic toxicity to aquatic insects. Another study to evaluate ERTT microbial toxicity has been completed and another study to evaluate DERT is in process. These studies will identify physio-chemical properties of erythromycin and determine the microbial toxicity of various erythromycin transformation products. Once again, these results will be used to address the concerns expressed by CVM. The last study to be considered is characterization of leaching of erythromycin from feed, feces, and sediment.

ADR# 311 –Lincomycin soluble powder for foulbrood disease in Honeybees

Waiting for the data summary for CVM submission. Dr. Margaret Oeller is assisting to facilitate this CVM submission.

Collaborative Projects:

ADR#280 - Fenbendazole in Game Birds (Pheasants, bobwhite quail, partridge)

See Southern Region Report.

Ms. Ogletree and Dr. Webb met in February 2008 and discussed concerns regarding the QA portion of this project. Dr. Webb will be submitting additional information.

Species Grouping Fish:

See North Eastern Region Report.

Sample analysis for florfenicol is complete and the two manuscripts have been accepted for publication.

ADR#324 – Progesterone CIDRs for Goats: Efficacy Study

See North Central Region Report.

The study protocol was submitted to CVM by Dr. Griffith. The UC Davis portion of the study is to be performed in Fall of 2009. UC Davis Animal Care and Use protocol for this study has been approved.

ADR#340 - Tulathromycin in Goats

QA review of the TAS protocol was done by Ms. Sandra Ogletree. The analytical method for plasma samples from goats was established and we analyzed 440 samples from the TAS and preliminary PK studies. Emphasis will now shift back to establishing and validating the tissue methods.

Other Projects:

Avian Species Grouping:

Kristy Cortright finished work on the *in vitro* and *in vivo* studies. She is completing work for her PhD.

CEFTIOFUR CRYSTALLINE FREE ACID

Excede in Goats:

In collaboration with Drs. Rowe and Angelos, Dr. Elizabeth Dore (UC Davis 3rd year Food Animal Resident) completed a study evaluating the use of Excede in lactating and non-lactating goats. The data from this study were compiled and presented at two scientific venues for which Dr. Dore received a resident award at one of the meetings. The serum and milk samples have been analyzed and the PK data modeled. Dr. Dore is currently working on the manuscript and the manuscript will be submitted to JVPT for publication.

New Projects:

Nothing to report at this time.

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:

The submission of the Milk Residue CIDR-G data to CVM and starting the CIDR-G Efficacy study are the primary goals. We will also continue to work to have the approved tulathromycin method established on the LCMS and begin analyzing samples for Dr. Griffith. Species grouping work for fish will continue, if the fish will consume the medicated Romet feed. Obtaining CVM concurrence for a florfenicol bioequivalence study will also be a major focus. Lasalocid avian food residue study to be performed in 2009.

Publications issued or manuscripts approved since the last meeting:

Lane, VM, Villarroel A, Wetzlich, SE, Clifford, A., Taylor, I and Craigmill, AL. (2007) Tissue residues of florfenicol in sheep. J Vet Pharmacol Therap, 31:178-180.

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, In Press.

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.

Principal Publications

Tort, M.J., A.J. Kuhl, G.A. Wooster and P.R. Bowser. 1998. Modification of tolerance of walleye (*Stizostedion vitreum*) to bath treatment with hydrogen peroxide. Journal of the World Aquaculture Society 29:499-504.

Saez, J.A. and P.R. Bowser. 2000. Hydrogen peroxide concentrations in hatchery culture units and effluent during and after treatment. North American Journal of Aquaculture 63:74-78.

Tripi, C.M. and P.R. Bowser. 2001. Toxicity of hydrogen peroxide to pre-exposed young-of-the-year walleye (*Stizostedion vitreum*): effects of water quality and age of fish. Journal of the World Aquaculture Society 32:416-421.

Tort, M.J., C. Jennings-Bayshore, D. Wilson, G.A. Wooster and P.R. Bowser. 2002. Assessing the effects of increasing hydrogen peroxide dosage on rainbow trout(*Onchorhynchus mykiss*) gills utilizing a digitized scoring methodology. Journal of Aquatic Animal Health 14:95-103.

Tort, M.J., D. Pasnik, C. Fernandez-Cobas, G.A. Wooster and P.R. Bowser. 2002. Quantitative scoring of gill pathology of walleyes (*Stizostedion vitreum*) exposed to hydrogen peroxide. Journal of Aquatic Animal Health 14:154-159.

Tort, M.J., C. Fletcher, G.A. Wooster, and P.R. Bowser. 2003. Stability of hydrogen peroxide in aquaria as a fish disease treatment. Journal of Applied Aquaculture 14:(3/4) 37-45.

Tort, M.J., G.A. Wooster and P.R. Bowser. 2003. Effects of Hydrogen Peroxide on Hematology and Blood Chemistry Parameters of Walleye (*Stizostedion vitreum*). Journal of the World Aquaculture Society 34:236-242

Tort, M.J., D. Hurley, C. Fernanzez-Cobas, G.A. Wooster and P.R. Bowser. 2005. Effects of hydrogen peroxide treatment on catalase and glutathione activity in walleye (*Sander vitreus*). Journal of the World Aquaculture Society 36(4):576-585.

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Abstracts:

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Bowser, P.R., R. E. Kosoff, C.-Y. Chen, G. A. Wooster, R. G. Getchell, A. Clifford, S.E. Wetzlich and A. L.Craigmill. 2007. Florfenicol Uptake and Depletion in Tilapia (*Oreochromis niloticus*) of Various Sizes. 32nd Eastern Fish Health Workshop. Gettysburg, PA. 19-22 June 2007.

REPORT FROM THE ADMINISTRATIVE ADVISORS – DR. L. GARRY ADAMS

Dr. Adams described the process of regional lobbying support at Ag Experiment Station level and the participation of Texas A&M, Cornell University and the University of California.

REPORT FROM THE NATIONAL COORDINATOR – DR. JOHN G. BABISH

The budget request process for multi-state funding from the Agricultural Experiment Stations was described by **Dr. Babish**. The FY09 request is for $335,000 and funding will be considered at the June meeting of Experiment Station Directors.

REPORT FROM FDA/CVM – DR. MEG OELLER

Dr. Oeller provided feedback and questioned each of the regional coordinators during their presentation.

FIVE-YEAR REVIEW ORGANIZATION

Selection of the three-person review committee was discussed along with the necessary time-line for completion. It was agreed that the National Coordinator will organize the three-member review team in November/December and complete the review in January through a series of teleconferences between the review team and NRSP-7. It was also agreed that the review team would consist of a representative of the Land Grant Colleges, the Pharmaceutical industry and stakeholders.

SPRING MEETING 2009

It was tentatively decided to hold the Washington, DC spring meeting in January on Monday and Tuesday the 26th and 27th of January with the primary purpose of the meeting to be the coordinate efforts among the University government relations groups in the four regions and inform stakeholders as to funding needs and federal budget progress.

OTHER BUSINESS

Southern region selection of a replacement regional coordinator was discussed with respect to the possibility of the selection including the relocation of the activity to another university in the southern region.

There being no other business, the meeting was adjourned at 4:45 pm.
Respectfully submitted:

John G. Babish, Ph.D. Date: 10/15/08
NRSP-7 National Coordinator