**MINUTES NRSP-7 SPRING MEETING 2007**
MARCH 6TH AND 7TH, 2007

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 March 6th and 7th at the FDA Center for Veterinary Medicine (CVM), 7529 Standish Place, Rockville, MD

**TUESDAY, MARCH 6TH 2007**
Deli Conference Room
7529 Standish Place, Suite 140 FDA/CVM,
Rockville, MD

ATTENDANCE AM MEETING
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. Arthur Craigmill (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. Kirklyn Kerr (University of Connecticut), Dr. Garry Adams, Chairman of Administrative Advisors (Texas A&M), Dr. David Thawley (University of Nevada), and Dr. John Baker (Michigan State University). The USDA representative is Dr. Gary Sherman (Washington, DC) and the FDA liaison is Dr. Meg Oeller (Rockville, MD). Dr. Lisa Tell, the Western Regional Coordinator-elect was also in attendance.

**8:30 – 9:00 REPORTS**
ADMINISTRATIVE REPORTS

USDA REPRESENTATIVE'S REPORT – DR. GARY SHERMAN
MUADP/NRSP-7 Funding - Multi-year budget funding system
Dr. Sherman presented an overview of the funding mechanism for the MUADP. In summary, research for the Minor Use Animal Drug Program is funded through a USDA special research grant administered by CSREES in cooperation with the NRSP-7 Technical Committee.

REPORT FROM THE ADMINISTRATIVE ADVISORS
The Administrative Advisors discussed the need for reexamination of the program's mission statement in regard to increased requirements and costs for drug approval without corresponding increases in funding. In this climate, it may be necessary to reconsider the prioritization and number of projects. The advisors also encouraged continued outreach to stakeholders noting that they can influence congressional support, which the committee cannot. They also encouraged development of a strong relationship between NRSP-7 and the Office of MUMS in CVM.

REPORT FROM THE NATIONAL COORDINATOR
Dr. Babish's report focused on revisiting NRSP-7 mission: Broadly stated, National Research Support Projects (NRSPs) are created to conduct activities that enable other important research efforts. The activity of an NRSP focuses on support activities, such as collecting, assembling, storing, and distributing materials, resources and information, or the sharing of facilities needed to accomplish high priority research. In accordance with the focus of NRSPs, the mission of the NRSP-7 Minor Use Animal Drug Program is:

- 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, NRSP-7 functions through the coordination of efforts among animal producers, pharmaceutical manufacturers, FDA/Center for Veterinary Medicine, USDA/Cooperative State Research, Education, and Extension Service, universities, state agricultural experiment stations and veterinary medical colleges throughout the country.

REPORT FROM DR. MEG OELLER

Dr. Oeller reported on the positive news that NRSP-7's public master files (PMF) have been used to support New Animal Drug Application (NADA) approvals for several oxytetracycline products for otolith marking of fry and fingerling fish. Another PMF for tylosin for American Foulbrood in honeybees also supported an approval this year. She noted acceptance of some significant studies for active projects. Also, the full transcript of the NRSP-7/FDA International Workshop on Minor Use and Minor Species is posted on the FDA/CVM website along with copies of the slide presentations. A translation into Spanish is being explored.

On the other hand, a problem remains with timely submission of data. Each regional coordinator was strongly encouraged to pressure investigators to complete study reports and notices of drug shipment as quickly as possible.

She also gave an update about the expected timing of the publication of regulations to implement the MUMS Act as well as the personnel changes in the Office of MUMS.

**9:00 – 9:30 REPORTS SUBMITTED ELECTRONICALLY TO BE INCLUDED IN THE MINUTES**

Reports from the regions and new projects:

**REGIONAL COORDINATORS' REPORTS**

***NORTHEAST REGION: DR. PAUL BOWSER***

WORK COMPLETED

Hydrogen Peroxide Project:

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

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 (would not accept the ration; 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 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.

Samples from all of the above noted Florfenicol studies are currently being analyzed in a cooperative effort with the Western Region NRSP7.

WORK PLANNED FOR THE COMING 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, with a focus on oxytetracycline during the coming year. These studies will be performed 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 salmonids and for the 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.

During the coming year we anticipate the completion of the remaining tissue assays for samples generated from Human Food Safety/Tissue Elimination Studies of Aquaflor (Florfenicol) in Hybrid Striped Bass and Tilapia.

Rofenaid in Pheasants INAD 10-804

We are considering the conduct of an efficacy trial of Rofenaid for the treatment of coccidia in pheasants.

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.

***NORTH CENTRAL REGION: DR. RONALD W. GRIFFITH***

Sheep CIDR-g Tissue Residue Stability

This study is being performed by Dr. Dennis Hallford at New Mexico State University in cooperation with both the Western and North Central Regions. The assays for the freezer stability of progesterone have been completed; the data has been reviewed by the NC Region coordinator and submitted to the Western Region for QA documentation. Conclusions of the tissue residue study are that exogenous progesterone results from the CIDR-g intravaginal insert are essentially zero 24 hours following removal of the CIDR-g. Fresh liver tissue has a high capacity for metabolizing progesterone. No residues were found in fresh (non-frozen) liver tissue spiked with exogenous progesterone and processed within 30 minutes of the addition of the progesterone. Progesterone is stable in frozen muscle tissues and frozen/thawed muscle tissues for at least 6 months following addition of exogenous progesterone. The data package from this study should be ready for submission to CVM shortly.

Goat CIDR-g Tissue and Milk Residue

The milk residue assay has been validated but the protocol for this study has not been written and obviously has not been submitted for review. Dr. Dennis Hallford is currently altering the sheep protocol to fit goats. He plans on doing both the in-life and analytical phase of the liver and muscle tissue portions of the study entirely at New Mexico State University using Boer-cross goats. For the milk residue portion of the study, he plans on doing the analytical phase but has requested that the in-life phase be done either by the Western or North Central Regions. He has demonstrated that progesterone is stable in frozen goat milk. As long as the milk is frozen shortly after (within 30 minutes) of collection, the assay should be valid.

Draxxin Efficacy in Goats

Two different protocols have been submitted to CVM for review. ONADE requested a natural exposure model in two different geographic locations within the U.S. using Arepresentative breeds@ and a total of 60 treated and 30 to 60 non-treated goats. ONADE also asked for antimicrobial susceptibility testing on at least 30 isolates of each bacterial species recovered from these goats. Texas A&M University will be one geographic site and Iowa State University will be the second site. A preliminary study this spring is planned to ascertain if enough goats can be Amanaged@ poorly enough to induce natural respiratory disease at a rate that will make this a practical study.

The second protocol submitted is a lung pharmacokinetic model. This study proposes to recover pulmonary fluids from treated goats over a period of time and then

assay these fluids for tulathromycin levels. This would be coupled with antimicrobial susceptibility testing of 50 to 100 isolates of *Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* species from diverse geographic locations within the U.S. The lung fluid samples will be obtained at Iowa State University and analyzed by LCMS at U.C., Davis. The antimicrobial susceptibility testing will be done at Texas A&M by Dr. Mitzy Libal.

Draxxin Target Animal Safety
The protocol has been submitted to CVM for review.

Draxxin Tissue Residue
The protocol has been submitted to CVM for review.

Lasalocid Efficacy in Pheasants
The protocol has been submitted to CVM for review. This study was originally going be done in cooperation with Dr. Thomas McQuistion. However, the number of pheasants required by ONADE for the study exceeded the capacity of the facilities at Milliken University. We are now planning on working with Dr. Larry McDougald at the University of Georgia. Inocula from two different geographic locations within the U.S. will be tested in two separate trials.

Bioclip in Sheep
No response from Merial to our inquiries.

Regulin (melatonin) implants for sheep
No activity to report. CEVA representative will be moving to Kansas City this spring. Contact will be made at that time to determine if CEVA is interested in supporting approval.

LCMS Purchase
Financial support is being provided for purchase of an LCMS for the Western Region Lab.

*WESTERN REGION: DR. LISA TELL*
PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:
**ADR #325 - Florfenicol for Sheep (Treatment for Respiratory Disease)** - During this reporting period the "Tissue Residue Depletion after Multiple Subcutaneous Administration of Florfenicol in Sheep" results were presented by Scott Wetzlich at the 10th EAVPT (European Association of Veterinary Pharmacology and Toxicology) meeting, September 17-22, 2006 in Turin, Italy. The MIC data that was submitted for this study was re-summarized, geographically mapped (to demonstrate regions in California that were represented) and resubmitted to CVM for review. We also requested that CVM review a historical product development call where it was stated that they would accept MIC data from Europe as part of the package. At this time, based on an informal response from CVM, it appears that we will not be able to progress any further with this project.

**ADR #324 - Progesterone CIDRs for Goats -** The Target Animal Safety Study Final Report is finished and is now undergoing quality assurance review. The development of the efficacy protocol is underway. Drs. Tell, Rowe, Griffith, and Craigmill have requested a conference call with CVM to receive guidance for the protocol.

**ADR #135 – Erythromycin in Salmonids -** FDA/CVM has contacted the Study Director, Dr. Christine Moffitt, stating that the Technical Section has been accepted as soon as there is an authorization letter from Abbott for CVM to use their proprietary toxicology

data as the basis for the ADI. Once that is established, the Technical Section Complete letters for effectiveness, target animal safety, and human food safety will be complete. Dr. Moffitt is also reviewing the draft Environmental Assessment Report.

**ADR # 311 –Lincomycin Soluble Powder For Treating Foulbrood Disease in Honeybees.** - Efficacy Study - a pilot study was reviewed and comments provided. The pivotal study was conducted at the same time and used the same protocol as the tylosin study, which was accepted. Final study report is pending. Target Animal Safety - Technical section completed (letter dated11/23/2001). Human Food Safety - Also done at the same time and used the same protocol as the tylosin study that was accepted. Final study report is pending. Dr. Oeller will submit a paper to address antimicrobial resistance (Guidance 152) and will also address the human gut flora issues. She will probably send all human food safety submissions in together. Environmental Assessment – Dr. Oeller will use the same Veterinary International Committee on Harmonization guidance that was used for the tylosin environmental submission.

COLLABORATIVE PROJECTS:
**ADR #280 - Fenbendazole in Game Birds** (Pheasants, bobwhite quail, partridge) - See report from the Southern Region by Dr. Alistair Webb.

**Species Grouping Fish Project -** During this reporting period there were no new samples submitted. There were 10 trials total. All feed and plasma samples from all trials have been analyzed. Muscle samples from 3 trials were completed this year. Muscle samples from 2 trials are pending (One of which is the abandoned trial). Sample analysis is ongoing. For more information please refer to the Northeast report by Dr. Paul Bowser.

**Progesterone CIDR for Sheep -** Ms. Sandy Ogletree is currently working on the quality assessment for the human food safety report sent from Dr. Dennis Halford.

NEW PROJECTS:

1. Working with Dr. Ron Griffith on the tulathromycin (DRAXXIN®) study in sheep and goats (see North Central Region Report).
2. Florfenicol in goats being pursued with Dr. Rowe.

WORK PLANNED FOR THIS YEAR (2007)

The completion of the projects listed above is the primary work planned for this year. If there are no funds identified for the 2007 fiscal year, the laboratory will go into “hibernation” mode. During this time, we will work on assay development using the liquid chromatography/mass spectrometer, finish the fish samples, and investigate the needs for the tulathromycin assay.

PUBLICATIONS ISSUED OR MANUSCRIPTS APPROVED SINCE THE LAST MEETING

Cortright, K.A. and Craigmill, A.L. Cytochrome P450-dependent metabolism of midazolam in hepatic microsomes from chickens, turkeys, pheasant and bobwhite quail. *J Vet Pharmacol Therap* **29**(6)469-476, 2006.

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

CURRENT PROJECTS

**RABBITS**

ADR – 107 Ivermectin & Rabbits - The in-vivo human safety has been completed and assay has been validated. Analyses of the incurred samples will be completed by winter and reports prepared for submission to FDA-CVM.

**FISH**

ADR - 271 Crude Carp Pituitary - The author has submitted a revised report that might address FDA-CVM's concerns.

ADR – 235 Ovaprim - UFL Tropical Fish [Roy Yanong] and Syndel are working with CVM to define needs. At present our only involvement is to provide GLP support for any TAS studies. This may be an alternative to CCPE as a spawning aid. There is no activity by the investigators.

ADR – 236 Metomidate - There is no activity by the investigator [Yanong UFL]

**BIRDS**

ADR - 280 Fenbendazole & Gamebirds - The TAS report continues to be incomplete but lacks investigator's final input and QA . We have received the Western Region's depletion assay results and are preparing a packet for submission to FDA-CVM.

**DEER**

ADR – 210 Fenbendazole & Red Deer & ADR – 216 Fenbendazole & Fallow - Intervet have indicated that they want to carry out a dose study before moving on this project

ADR - 294 Lasalocid And Deer / ADR - 298 Lasalocid And Goats - Problem is that Alpharma will only proceed if there is a zero withdrawal time. We are starting to mount an assay and will carry out initial pilots on two deer and two goats to see if the lasalocid levels are below tolerance.

WORK PLANNED FOR THE COMING PERIOD

- Maintain lab and staff at GLP level
- Submit early in the new year the all ivermectin for rabbit reports and all fenbendazole reports.
- Organize 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 full activation of the RUSTi database.

WEB SITE MAINTENANCE

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 now fully functional and Laura has returned to full-time work. We will be working with each coordinator to get active projects fully entered into the system.

NEW / PROPOSED PROJECTS:

With no funding in sight, no new projects are under consideration with primary effort being made to complete existing studies.

**9:45 – 12:00** Development of discussion strategy with FDA/CVM for PM meeting

DISCUSSION POINTS TO DEVELOP FOR PM MEETING WITH CVM

i. Bridging studies in regard to analytical methodology - discussion of need and logic behind them.
ii. Pharmacokinetics and MIC data for effectiveness
iii. TAS and Efficacy Studies – Issues?
iv. Pharmacokinetics in target animal safety studies
v. Environmental assessments for aquaculture

Fall Meeting – It was decided to have the fall meeting at Intervet, Inc, Millsboro, DE on September 27th and 28th.

Other Issues – No other issues were brought forward

**12:00 – 1:00 LUNCH**

ATTENDANCE PM MEETING

| NAME | AFFILIATION | EMAIL ADDRESS |
|---|---|---|
| A. Adams | CVM/ONADE/HFV-131 | Aadams1@cvm.fda.gov |
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| Paul Rodgers | American Sheep Industry Assn | prodgers2@earthlink.net |
| Ron Griffith | NRSP-7 | rgriffit@iastate.edu |
| Roz Schnick | MSU | RozSchnick@centurytel.net |
| Sibyl Wright | USDA/FSIS | SIBYL.WRIGHT@FSIS.USDA.GOV |
| Susan Storey | CVM/ONADE/HFV-131 | sstorey@cvm.fda.gov |

PM MEETING
**1:00 – 5:00 MEETING WITH FDA/CVM REPRESENTATIVES**

**FDA/CVM Meeting Room**
**Office of the Director, Room 152**
**Building 7519**

**INTRODUCTIONS**

OUTLINE OF MEETING AND OBJECTIVES

DR. JOHN G. BABISH – Dr. Babish presented the format of the afternoon's meeting describing the question and answer format to be used regarding specific questions to FDA/CVM reviewers.

HISTORICAL PERSPECTIVE ON NRSP-7 FROM THE BIG BANG TO PRESENT

DR. "JURASSIC" ART CRAIGMILL – Dr Craigmill presented an historical perspective of the program with recommendations for the future based upon his experiences in the Western Region for nearly twenty years.

DISCUSSION TOPICS FOR THE AFTERNOON

i. Bridging studies in regard to analytical methodology - discussion of need and logic behind them.
ii. Pharmacokinetics and MIC data for effectiveness
iii. TAS and Efficacy Studies – Issues?
iv. Pharmacokinetics in target animal safety studies
v. Environmental assessments for aquaculture

A generally frank and open discussion was held between the regional coordinators and the FDA/CVM reviewers on each of the above topics as they related to individual projects within their regions. All agreed that the interaction was helpful and should be repeated on a regular basis.

**Wednesday March 7th, 2007**
Deli Conference Room
7529 Standish Place, Suite 140 FDA/CVM,
Rockville, MD

**ATTENDEES**: FDA/CVM liaison, NRSP-7 Administrative Advisors & Technical Committee, Stakeholders representing sheep, goats, game birds, pharmaceutical corporations, and the animal health industry.

Meeting focused on the re-examination of expectations for the development of drug information and drug approvals in minor species by NRSP-7 in light of FDA/CVM current requirements and MUMS.

**9:00 – 11:45**

Representative

- American Veterinary Medical Association – Dr. Mark Lutschaunig (Invited)
- Sheep Industry – Mr. Paul Rodgers (Invited)
- Goat – Ms. Linda Campbell (invited)
- Aquaculture – Ms. Roz Schnick (Invited)
- Game bird Industry – Dr. Eva Pendleton(Invited)

ATTENDEES

| NAME | AFFILIATION | EMAIL ADDRESS |
|---|---|---|
| Alistair Webb | NRSP-7/U FL | Webb@ufl.edu |
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| Roz Schnick | MSU | RozSchnick@centurytel.net |
| Susan Storey | CVM/ONADE/HFV-131 | sstorey@cvm.fda.gov |

INTRODUCTIONS

WELCOME – DR. BERNADETTE M. DUNHAM, Director, Office of Minor Use Minor Species.

Dr. Dunham outlined the objectives and function of the Office of Minor Use Minor Species. She further described the future plans of the Office to provide funding for research into the approval of drugs for minor species or minor uses. These funds have currently not been approved by Congress, but the expectations are that they will be approved in the next round of Congressional funding.

OUTLINE OF MEETING AND OBJECTIVES –
DR. JOHN G. BABISH, National Coordinator MUADP/NRSP-7.

Dr. Babish outlined the objects for the meeting that included an introduction of the interactions between the MUADP and CVM and selection of projects.

MINOR USE HISTORICAL PERSPECTIVES ON NRSP-7 FROM THE BIG BANG TO PRESENT

DR. "JURASSIC" ART CRAIGMILL - Dr Craigmill restated his historical perspective of the program with recommendations for the future based upon his experiences in the Western Region for nearly twenty years.

DISCUSSION POINTS WITH STAKEHOLDERS

i. Clarification of NRSP-7 mission
ii. Selection of projects;
iii. Environmental assessments for aquaculture

Dr. Babish's revisited the NRSP-7 mission: Broadly stated, National Research Support Projects (NRSPs) are created to conduct activities that enable other important research efforts. The activity of an NRSP focuses on support activities, such as collecting, assembling, storing, and distributing materials, resources and information, or the sharing of facilities needed to accomplish high priority research. In accordance with the focus of NRSPs, the mission of the NRSP-7 Minor Use Animal Drug Program is:

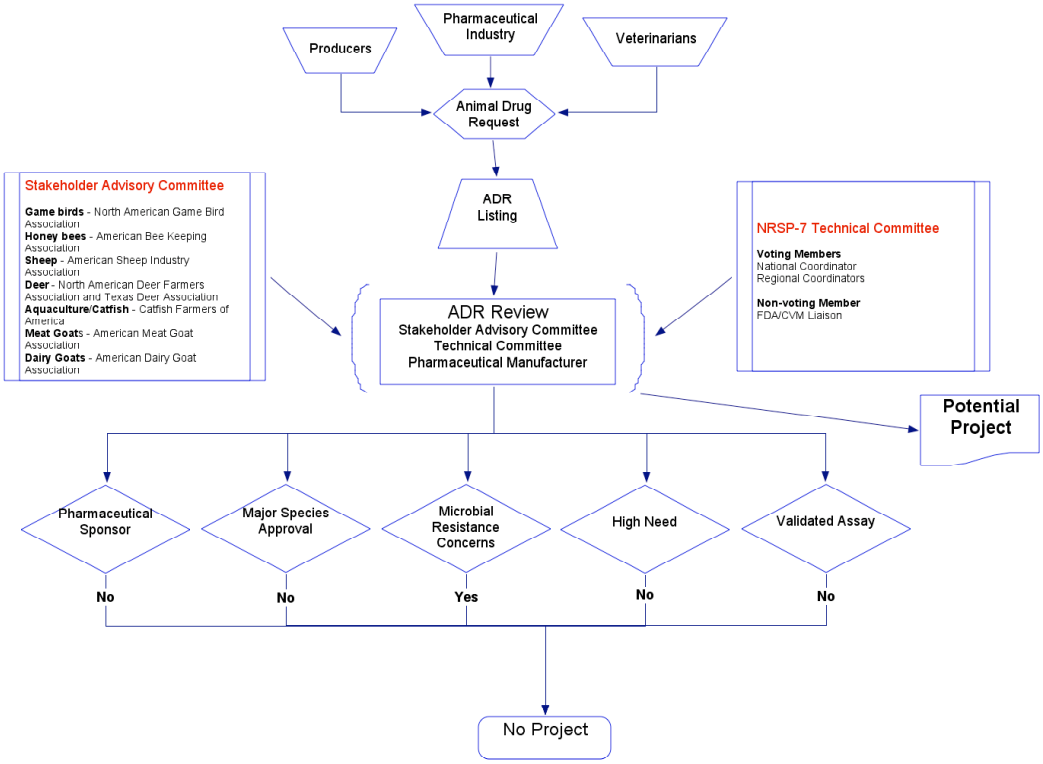
- Identify animal drug needs for minor species and minor uses in major species,
- Generate and disseminate data for safe and effective therapeutic applications, and
- Facilitate FDA/CVM approvals for drugs identified as a priority for a minor species or minor use.

To accomplish these goals, NRSP-7 functions through the coordination of efforts among animal producers, pharmaceutical manufacturers, FDA/Center for Veterinary Medicine, USDA/Cooperative State Research, Education, and Extension Service, universities, state agricultural experiment stations and veterinary medical colleges throughout the country.

The process for selection of drugs for testing in NRSP-7 is represented schematically in Figure 1. 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. An example of the information requested for an ADR is provided in Appendix A. This 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 potential projects.

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



**11:30 – 12:30 LUNCH**

**12:30 – 4:00 CONTINUED DISCUSSION**

*The Goat Industry Overview and Therapy Needs*
Ms. Linda Campbell was supposed to present information about the American dairy goat, but was prevented by a family emergency. She did provide the committee with a copy of her slides that will be helpful for certain questions of management and therapeutic needs, but no substitute for an in-person presentation and discussion. She will be invited again next year.

NATIONAL NADA COORDINATOR FOR AQUACULTURE
Roz Schnick described the achievements of several different entities, including the Upper Midwest Environmental Sciences Center, conducting studies to support drug approvals. Roz reported significant progress on projects exploring claims for Aqui-S™ (anesthetic), chloramine-T, Florfenicol, formalin, hydrogen peroxide, 17 alpha methyltestosterone, and oxytetracycline. She also described a survey that she conducted to identify unmet label claims in the public sector. Results will soon be distributed to the 38 participating states through the Drug Approval Working Group. Ms. Schnick also described her internet-based drug matrix database, which provides general information and reports on the status of studies supporting aquaculture drug development.

OTHER BUSINESS
They're being no other business, the meeting was adjourned.

RESPECTFULLY SUBMITTED:

John G. Babish, Ph.D. Date: 5/1/07
NRSP-7 National Coordinator