MINUTES NRSP-7 SPRING MEETING 2006

MAY 11TH AND 12TH. 2006



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 May 11 at the FDA Center for Veterinary Medicine (CVM) in Rockville, MD.

ATTENDANCE

The NRSP-7 technical committee is made up of a National Coordinator, 4 Regional Coordinators, 4 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 (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. Craigmill was unable to attend and was represented by his Regional Coordinator-elect, Dr. Lisa Tell. Dr. Kerr was also unable to attend. This meeting was attended by the National NADA coordinator for Aquaculture, Rosalie "Roz" Schnick as well as by stakeholders and several reviewers and managers from FDA/CVM.

OPENING REMARKS FROM DR. BEAULIEU

The director of the CVM's new Office of Minor Use and Minor Species Animal Drug Development (OMUMS), Dr. Beaulieu, welcomed everyone and discussed issues of major importance to CVM. These include the implementation of the Minor Use Minor Species Animal Health Act, a budget forecast, Animal Drug User Fees, Minor Use issues, and the upcoming personnel changes in the Office. He reported that the drafting of implementing regulations for provisions of the MUMS Act is moving forward. The final rule for "designation" will publish soon as will the proposed rule for "indexing". The determination of "minor use in a major species" is being handled on a case-by-case basis until proposed rules are published to help clarify this issue. Budget constraints may delay the establishment of a grant program for "designated" MUMS drugs. Funding is authorized for a grants program once the designation final rule is published, but it does not look like the funds will be appropriated for a while. User fee waivers are available for minor species projects, and hopefully will still be so when the fees are reauthorized by Congress. Dr. Beaulieu will be retiring in January of 2007 after serving as a champion of MUMS issues for many years. The new Director will be Dr. Bernadette She will begin working with Dr. Beaulieu this fall to provide a smooth transition.

STAKEHOLDERS PRESENTATIONS

The Deer Industry Overview and Therapy Needs

The NRSP-7 Program's last 5-year review recommended that the NRSP-7 committee do more outreach to stakeholders. To forward that goal, the committee decided to invite prominent members of minor species industries to speak at the spring meetings to foster better communication. This year the committee invited Dr. C. Shane Donley, a





veterinarian from Ohio who represented the farmed deer industry. From his early life growing up on a deer farm to his current life in veterinary practice with many deer farm clients, Dr. Donley is well versed in the practices and problems associated with raising deer. He provided an excellent picture of the deer industry that included husbandry practices and veterinary drug needs for management and disease treatment. His insightful and thorough presentation was very helpful to the NRSP-7 committee and will be invaluable in the selection of projects and the design of needed studies.

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 gave a presentation, "Aquaculture Drug Approval Highlights of Progress". She 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.

ADMINISTRATIVE ADVISORS' REPORT

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.

USDA REPRESENTATIVE'S REPORT

Dr. Gary Sherman introduced his associate, Jillian Allen, who has been assisting him in his work with the NRSP-7 program. He provided an update on responsibilities and personnel changes in his office at USDA. He related that the program's funding is expected to remain at the same level for the foreseeable future. He also discussed the timing and methods for managing NRSP-7 grants in the 4 regions.

This was the first NRSP-7 meeting for Dr. Sherman since replacing Dr. Larry Miller who served in this role for many years. Dr. Miller was honored at a dinner with the committee that evening. His contributions to the program cannot be overstated.

FDA'S NRSP-7 LIAISON REPORT

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.

NATIONAL COORDINATOR'S REPORT

Dr. Babish reported on the need for more outreach to stakeholders to solicit increased funding of the program. He led a discussion about increasing needs in a time of decreasing resources.

REGIONAL COORDINATORS' REPORTS Northeast Region: Dr. Paul Bowser

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 based on this project has been published in the peer-reviewed scientific literature. 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 20C

Florfenicol:

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

Data from these species will be compared to data currently available where 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; 10 mg drug/kg fish/day for 10 days) as a model compound, with studies completed in walleyes (20C, 25C), tilapia (25C, 30C) and hybrid striped bass (20C, 25C).

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 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

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

Usefulness of the findings:

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.

North Central Region: Dr. Ronald W. Griffith

1. CIDRg in sheep:

Dr. Dennis Hallford at New Mexico State University has submitted the results of the tissue residue study to CVM. CVM has requested additional data on the stability of progesterone in liver and muscle tissues of normal ewes to demonstrate that there was no loss of progesterone in these tissues when stored frozen for up to 6 months. Dr. Lynn Friedlander at CVM recently gave us some guidance as to the specifics of the stability assays that were needed. Dr. Hallford has submitted a draft protocol for the stability study to CVM for review. A teleconference to discuss the protocol is being scheduled. Dr. Hallford is currently preparing to collect tissues and would like to begin the stability study at the end of May 2006 if possible.

2. CIDRg in goats:

The Western Region is taking the lead in this project. Dr. Hallford has obtained normal goat milk and has reported that he is nearly ready with the validation of progesterone in milk. He has not yet attempted the validation in goat meat and liver. The North Central Region will help out with this project as needed.

3. Nuflor in veal calves:

No current activity with these studies.

WESTERN REGION: DRS. ARTHUR L. CRAIGMILL/LISA TELL

ADR#325 - Florfenicol for sheep for respiratory diseases.

Project is on hold awaiting confirmation of additional data required. Funds expended to date on this project exceed \$200,000 of Western Region expenses. Of interest in this process is that the time and money spent on method validation exceeded the amount spent on analyzing the actual samples.

ADR#324 - Progesterone Ciders for goats.

The TAS study is complete and we are awaiting a report from the principal investigator.

ADR#272 - Romet for gamebirds.

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 market substrate.

ADR#299 - Pirlimycin for dairy goats.

No progress since last meeting.

ADR#295 - Strontium chloride for Salmonids.

Nothing to report from Steve Schroeder the Pl.

ADR#311 - Lincomycin for honeybees

Data were accepted by CVM and a Public Master File has been published.

SOUTHERN REGION: DR. ALISTAIR I. WEB

The GLP inspections of our ivermectin assay and *in vivo* sections by the Western Region have been completed and all issues addressed satisfactorily.

RABBITS

ADR #107 Ivermectin & Rabbits

The assay has been validated and the *in vivo* depletion stage is completed. The assay is being bridged with beef [species the residue method was developed in].

FISH

ADR #271 CRUDE CARP PITUITARY

The TAS report has not found favor with FDA. The author is preparing a rebuttal and we will see if the report is salvageable. What is group's view on funding any repeat on the project given this and low likelihood of a manufacturer being found.

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.

ADR #236 metomidate

Following a teleconference with CVM, UFL Tropical Fish [Roy Yanong] has been evaluating behavioral changes as markers of efficacy of metomidate for sedation during transport. Pilot studies have not been promising. This may push them back to studying cortisol depression as an index of stress relief. My anesthesiologist hat is concerned as this group of drugs has a potent depressant effect on adrenal function in mammals, which would confound their study.

BIRDS

ADR #280 FENBENDAZOLE & GAMEBIRDS

The TAS report is nearly complete but lacks investigator's final input and QA. 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 had an in-person conference with CVM and Intervet to spell out requirements but Intervet is seeking more clarification – especially TAS kinetic requirements. 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 but has cooling ardor. Intervet have limited their interest to white tailed deer but I have made it clear to FDA NRSP-7's goal is for "Cervid". In the conference studies of WTD, red deer/elk and fallow deer would gain a "Cervid" label.

ADR #294 Lasalocid And Deer / ADR #298 Lasalocid And Goats

A teleconference was held November 18th 2005 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 UFL. Problem is that Alpharma will only proceed if there is a zero withdrawal time

FRIDAY MAY 12[™], 2006

Woodfin Suite Hotel 1380 Piccard Drive Rockville, MD Phone: 301-590-9880 www.woodfinsuitehotels.com

FRIDAY MAY 12, 2006

The USDA's Minor Species Animal Drug Program, National Research Support Project #7 (NRSP-7) held its second day of the semi-annual meeting of the technical committee and administrative advisors on May 12th at the Woodfin Suite Hotel 1380 Piccard Drive, Rockville, MD.

ATTENDEES

In attendance were the National Coordinator Dr. John Babish (Cornell University), Regional Coordinators 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 Dr. Garry Adams (Texas A&M), Dr. David Thawley (University of Nevada), and Dr. John Baker (Michigan State University); the USDA representative Dr. Gary Sherman (Washington, DC) and the FDA liaison Dr. Meg Oeller (Rockville, MD). Dr. Craigmill, represented in person by his Regional Coordinator-elect, Dr. Lisa Tell was present through teleconferencing. Dr. Kerr was unable to attend.

9:00 - 11:30

WORKING SESSION

Drs G. Adams and J. Babish - Recap of NRSP-7 Mission and Outline Discussion Points Drs. Adams and Babish lead a discussion on funding and inflation: the inflation rate from Jan 1996 to Jan 2006 was 28.34%. Since our funding has remained stabile, NRSP-7 has absorbed a nearly 30% reduction in programmatic funding. This brings up the necessity of getting more funding, or shifting our priorities. With increasing costs and requirements for getting required studies completed for approval, it is time to reconsider the program goals.

If sufficient money is not available to get approvals, then NRSP-7 needs to focus on getting the data necessary so that the drugs can be used safely in an extra-label manner. An analysis of funding allocations indicates that NRSP-7 spends more money on tissue assay validation than on the actual tissue sample analysis; perhaps NRSP-7 should validate the assay as would be done for a typical scientific study than for FDA/CVM and do the residue studies. This option is something that must be seriously considered.

The situation with regards to funding is critical. NRSP-7 does not have the funding to offer approvals to FDA/CVM similar to those submitted by industry. These observations were underscored by our external reviewers during our five-year review. NRSP-7 has repeatedly stated in our annual reports and presentations that providing the information on safety and efficacy to the stakeholders is one of our primary missions. Getting this information out to the stakeholders via publications, presentations and FARAD should be emphasized in our achievements and progress summaries. Obtaining an FDA approval is a secondary, albeit, significant goal.

PROGRESS AND NEW/PROPOSED PROJECTS:

NORTHEASTERN - DR. PAUL BOWSER

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 tissue assays for samples generated from Human Food Safety/Tissue Elimination Studies of Aquaflor 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 - DR. RONALD W. GRIFFITH

Draxxin in sheep and goats:

Pfizer has requested that NRSP-7 provide data to support the approval of Draxxin (tulathromycin) in sheep and goats. A respiratory disease claim is being sought for both animal species. The North Central Region is preparing protocols for the pharmacokinetic studies, etc., and will schedule a product development meeting with ONADE as soon as possible. A protocol for a Target Animal Safety study was written in cooperation with Dr. Kevin Washburn at Texas A&M University but Dr. Washburn decided to perform a non-GLP study on his own in the summer of 2006. The protocol has been modified to perform the study at lowa State University. The analysis phase of the studies is to be performed in the Racing Chemistry Section at the Iowa State University Veterinary Diagnostic Laboratory. The analytical method is being provided by Pfizer and is an LCMS analysis.

Regulin in sheep:

Regulin is a melatonin implant used in Europe and Australia to enhance early onset of estrus in ewes. Sheep are seasonally polyestrus and do not usually cycle until day length is decreasing. Regulin initiates early cycling, most likely by altering the perception of the ewe concerning day length. Regulin is often used in combination with Fecundin to increase the number of lambs conceived per ewe. Fecundin affects the reproductive rate by immunizing ewes against androstenedione and perturbing the ovarian-pituitary feedback system. Regulin is produced in Europe by CEVA SANTE ANIMALE. We have contacted CEVA and their representative, Dr. Dominique Thibaud has expressed an interest in working towards U.S. approval for the implants. The numbers of sheep in the U.S. are significantly below those in most of the countries of the EU, thus the financial impact of U.S. approval is not great for CEVA.

Bioclip in sheep:

Bioclip is an epidermal growth factor used for inducing a wool-break in sheep. The wool break causes sheep to shed their wool. The product is licensed in Australia for use in shearing sheep. The sheep are encased in netting and the fleece is removed from the sheep about 1 month following injection of the Bioclip. The product works in Merino and half-Merino sheep. Damage to the skin of the sheep is avoided because the procedure does not involve mechanical shearing. Also, Bioclip results in a very uniform fleece length and prevents "second cuts" that decrease the value of the fleece. Merial has the rights to the product. Merial has been contacted to see if they have any interest in working with NRSP-7 on U.S. approval of Bioclip, but not answer has been received as of this date.

Lasalocid in ring-necked pheasants:

This project has been delayed several times as we waited for information concerning the EU approval of lasalocid in gamebirds. Alpharma has recently provided that information and a product development meeting needs to be scheduled with ONADE. Dr. Thomas McQuistion at Milliken University has agreed to conduct efficacy studies for lasalocid in ring-necked pheasants and is currently collecting *Eimeria* species from pheasants to be used as challenge inoculum in 2007. The protocol has been written for the efficacy study. The remainder of the studies will probably be performed at lowa State University.

WESTERN - DRS. ARTHUR L. CRAIGMILL/LISA TELL

The completion of the ongoing projects is the primary work planned for next year. The western region will continue with the avian 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 if the sponsor Pfizer is willing.

Spectramast[™] LC sterile suspension for mastitis in dairy goats.

This project is ready to proceed with the support of Pfizer, and we need to establish an ADR number and find a PI to do the work.

SOUTHERN - DR. ALISTAIR I. WEBB

Fasinex® in deer continues to interest us but gathers dust while we see how other deer projects go. 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

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 now fully functional so I will be working with each coordinator to get active projects fully entered into the system. We have some delays as our biological scientist is taking Family Medical Leave through September.

Work Planned for the remainder of the Year:

- 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.

FALL MEETING

Dr. Griffith reminded all about the October 10th and 11th 2006 meeting in La Crosse, WI and that rooms need to be reserved by September 18th. The Holiday Inn Express, in Onalaska, WI (608-783-6555) is holding a bank of rooms until that date.

OTHER BUSINESS

There being no other business, the meeting was adjourned.

RESPECTFULLY SUBMITTED: John G. Babish, Ph.D. NRSP-7 National Coordinator

Date: 8/1/06