MINUTES OF NRSP-7 SPRING MEETING 2005
Kelly's Deli Conference Room,
7500 Standish Place FDA/CVM,
Rockville, MD
May 19th and 20th, 2005

LOCATION: Kelly's Deli Conference Room, 7500 Standish Place FDA/CVM, Rockville, MD
DATE: Thursday May 19th 2005
ATTENDEES: FDA/CVM reviewers, NRSP-7 Administrative Advisors & Technical Committee, Paul Rodgers and Dr. Cindy Wolf of the American sheep Industry Assn and Dr. Denise Petty of the University of Florida for the ornamental fish industry.

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WELCOME
Dr. Stephen Sundlof provided the welcoming presentation focusing on the progress in the legislative arena for the Minor Use Minor Species Act (MUMS). He concluded by stating that currently there are only a few hurdles that all involved believe will be addressed in the next year.

MINOR SPECIES SPOTLIGHT: This year the NRSP-7 Spring program focused on the ornamental fish and sheep industries.

INVITED SPEAKERS

ORNAMENTAL FISH INDUSTRY

At the request of the five-year review committee for consideration of non-food minor species in the NRSP-7 program, at representative of the ornamental fish industry was invited to speak at our spring meeting. Dr. Denise Petty of the University of Florida gave a presentation for the ornamental fish industry. Her presentation described the importance of the industry to Florida agriculture and emphasized the need for good data on the safety and efficacy of therapeutics.

THE SHEEP INDUSTRY

Mr. Paul Rodgers and Dr. Cindy Wolf provided background on the sheep industry in the U.S. and outlined a priority of requests for both therapeutic and production drugs.

DISCUSSION SESSION

Following the presentation, the remainder of the morning was spent in the discussion of how best to coordinate the resources of MUMS and NRSP-7 Minor Use Drug Program in addressing the needs of the ornamental fish and sheep industries.

OUTSIDE REPORT

NATIONAL NADA COORDINATOR FOR AQUACULTURE

Roz Schnick gave a presentation describing 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. 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 REPORTS

REPORT FROM THE ADMINISTRATIVE ADVISORS - DR. DONALD ROBERTSON

The Administrative Advisors discussed the need for continued outreach to stakeholders.

REPORT FROM USDA-CSREES - DR. LARRY MILLER

Dr. Miller related that the program's funding has been continued at its present level in the 2006 budget.

REPORT FROM CVM - DR. MEG OELLER

The Minor Use/Minor Species Animal Health Act (the MUMS Bill) was discussed. If enacted, this legislation would make incentives available to pharmaceutical sponsors, allow for conditional approval of MUMS drugs, and allow legal marketing of some products for non-food producing animals under an indexing system.

The impact of the Animal Drug User Fee Act was also explored. The NRSP-7 program was again able to procure a waiver of sponsor fees for fiscal year 2005 based on the fact that all projects are for minor species. Sponsors who use NRSP-7 Public Master Files to support their New Animal Drug Applications will need to request waivers

of filing fees prior to submitting their applications. The improved efficiency of drug evaluation from user fees is expected to benefit all applications, whether they are charged fees or not.

Dr. Meg Oeller also reviewed current activities at CVM for each active project.

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

Dr. Babish reported on the annual report for the program and the continuing progress on fulfilling the recommendations of the 5-year review in the areas of electronic tracking of projects, and higher visibility to solicit increased funding of the program.

Reports from the regions - Current work on active projects

NORTHEASTERN - DR. PAUL BOWSER

1. Human Food Safety Studies of OXYTETRACYCLINE in Fish. (INAD 10-319) - Human food safety/tissue elimination kinetics studies of oxytetracycline have been completed in tilapia (25C, 30C), walleye (15C, 20C), summer flounder (17C, 20C), and hybrid striped bass (20C, 25C). All tissues samples have been processed and several manuscripts based on this comparative pharmacokinetics study have been published or have been submitted for publication in the peer-reviewed literature.

2. Human Food Safety Studies of ROMET-30 in Fish. (INAD 10-823) - Human food safety/tissue elimination kinetics studies of Romet-30 have been completed in tilapia (25C, 30C), summer flounder (17C, 20C), and walleye (20C, 25C). All tissues samples have been processed and data have been analyzed. Human food safety/tissue elimination kinetics studies of Romet-30 were initiated in hybrid striped bass at 20C. Problems were experienced with a lack of palatability of the medicated feed by the hybrid striped bass. In spite of several attempts to circumvent this palatability problem, no solution to this problem could be found. We have recently learned that the manufacturer has developed a means of circumventing the palatability problem with this therapeutant. As a result, we anticipate performing human food safety trials with the modified Romet-30 product. A manuscript describing the work performed in tilapia, walleye and summer flounder is being prepared for submission to the peer reviewed literature.

3. Human Food Safety Studies of Aquaflor (FLORFENICOL, Schering-Plough) in Fish. (INAD 11-145) - Human food safety/tissue elimination kinetics studies of Aquaflor (Florfenicol, Schering-Plough) have been completed in tilapia (25C, 30C), and walleye (20C, 25C). All tissues samples for tilapia have been analyzed. Samples from walleye are in the process of being analyzed.

NORTH CENTRAL - DR. RONALD W. GRIFFITH

1. Pharmacokinetics of FLORFENICOL in Veal-Age Calves: The pharmacokinetics of florfenicol in veal-age calves were evaluated by both the subcutaneous and intramuscular routes. Three groups of 10 calves each were injected by either the SC or IM routes and the calves bled for serum over various periods for 96 hours. The NRSP-7 Western Region laboratory for florfenicol levels analyzed the sera. The data are currently being analyzed and compared to Aadult@ pharmacokinetic values. A manuscript is being prepared for publication.

2. CIDR-g (Progesterone) Tissue Residue in Sheep: Dr. Dennis Hallford of New Mexico State University completed the in-life phase of this study. Validation of the assays was performed and the validation approved by the Center for Veterinary Medicine/FDA. Dr. Hallford is currently performing tissue levels of progesterone for the liver and muscle tissue.

WESTERN - DR. ARTHUR L. CRAIGMILL

1. FLORFENICOL/sheep (ADR #325): The final report "Pharmacokinetics of Nuflor® in Sheep" was submitted and reviewed by FDA/CVM. The MIC study has been completed and the final report is in preparation. The Human Food Safety portion was completed and the tissues are currently undergoing analyses and are nearing completion. The method validation has been completed for all tissues.

2. PROGESTERONE CIDRg/sheep (ADR #258): The target animal safety portion was completed and the final report was submitted to FDA/CVM for review.

3. FENBENDAZOLE/game birds (ADR#280): (collaborative project with the Southern Region): Method validation has been completed and the final report was submitted to FDA/CVM for review and accepted.

4. ROMET-30 in fish (ADR#313): (collaborative project with the North East Region) The Western region laboratory has completed the sample analyses and the results were sent to the North East Region office. The data are currently being evaluated**.**

5. CEFTIOFUR/llamas and alpacas (ADR #275): Publication of "Pharmacokinetics of Ceftiofur in Llamas and Alpacas" was published in the *Journal of Veterinary Pharmacology and Toxicology (JVPT)* **27**(1)13-20, 2004.

6. CEFTIOFUR/Red Deer (ADR #251): Publication of "Pharmacokinetics of Ceftiofur in Red Deer" was published in the *Journal of Veterinary Pharmacology and Toxicology (JVPT)* **27**(1)7-11, 2004.

7. LINCOMYCIN/Bees (ADR #311): Target animal safety report has been accepted by FDA/CVM.

8. TYLOSIN/Bees (ADR #217): The Public Master File for Tylosin in Bees has been published (Federal Register: August 3, 2004 (Volume 69, Number 148).

9. SPECIES GROUPING - Comparative metabolism studies continue, in vivo pharmacokinetic studies are underway, and a preliminary PBPK model has been developed for the chicken, and anatomical data (organ weights) collected on the other species.

Residue Analysis Statistics

2004		
2633 Samples Received	1307 Samples Analyzed (50%)	Samples Remaining (50%)
371 from study 03-329-EFF (Nuflor Veal Calf)	144 from study 03-329-EFF (Nuflor Veal Calf)	106 from study 2004-1 (Nuflor Tilapia)
252 from study 2004-1 (Nuflor Tilapia)	146 from study 2004-1 (Nuflor Tilapia)	78 from study 2004-3 (Nuflor Walleye)
231 from study 2004-2 (Nuflor Tilapia)	231 from study 2004-2 (Nuflor Tilapia)	165 from study 2004-4 (Nuflor Walleye)
30 from study 04-INT-1 (Romet Elephant)	30 from study 04-INT-1 (Romet Elephant)	750 from study 04-INT-2 (Midazolam Birds)
268 from study 2004-3 (Nuflor Walleye)	190 from study 2004-3 (Nuflor Walleye)	
246 from study 2004-4 (Nuflor Walleye)	81 from study 2004-4 (Nuflor Walleye)	
162 from study 04-INT-3 (Naxcel Veal Calf)	162 from study 04-INT-3 (Naxcel Veal Calf)	
23 from study 2004-5 (Nuflor Tilapia)	23 from study 2004-5 (Nuflor Tilapia)	
1050 from study 04-INT-2 (Midazolam Birds)	300 from study 04-INT-2 (Midazolam Birds)	

	2003	
	437 Samples Analyzed (36%)	
	240 from study 2003-3 (Nuflor Tilapia)	
	197 from study 02-325-HFS (Nuflor Sheep)	

Quality Assurance Inspections
Quality Assurance Officer – Ms. Sandra Ogletree

1. ADR-325: Nuflor® (Florfenicol) Injectable Solution for the Treatment of Respiratory Disease in Sheep.

Inspections - November 9, 2004. QA inspection of the laboratory analysis of sheep tissues (kidney).

SOUTHERN - DR. ALISTAIR I. WEB

1. ADR – 107 IVERMECTIN in rabbits - Assay is under validation and was inspected for GLP compliance earlier this month. The assay will bridge with beef, which was the species the residue method was developed in. It is estimated that the in vivo work will commence in July and Ms Ogletree Davis will return to inspect the in vivo stage as well as review any corrective action taken from her initial QA.

2. ADR – 271 CRUDE CARP PITUITARY - The Target Animal Safety report has been submitted to FDA/CVM.

3. ADR - 280 FENBENDAZOLE in gamebirds - The efficacy material has been accepted by CVM. The first draft of the TAS report has just been completed and while reviewing it we are also finalizing the in vivo section of the human safety work. As promised last meeting this WILL be submitted by summer's end.

4. ADR – 210 FENBENDAZOLE & Red Deer and 5. ADR – 216 Fenbendazole & Fallow Deer - After being inactive for several years this has been on hold and we are having a teleconference with CVM and Intervet. An investigator has been identified for the TAS and human safety work [UF Zoo Vet – Ramiro Isaza] and Dr. Bermingham is our contact and infers they [Intervet] have money to help with the project.

5. ADR - 294 LASALOCID in Deer and

6. ADR - 298 LASALOCID in Goats - This was inactive but suddenly Alpharma are interested.

Additional Work

1. Southern region lab and staff upgraded to GLP level
2. Submit the ivermectin TAS report for rabbit, start ivermectin assay, and repeat the ivermectin depletion study.
3. Revive, plan, initiate and organize studies for gaining approval of fenbendazole and lasalocid in deer, and lasalocid in goats.
4. Investigate in vivo efficacy studies for coccidiosis in game birds.
5. 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.
6. Continued collaborative work with the other regions is anticipated and may include unplanned studies to address critical needs and opportunities to collect data.

7. Continue the development of the NRSP-7 web site with evaluation of the MUMSRx database.

Web Site

The NRSP-7.org web has been moved to a new server. The MUMSRx web database continues to be updated, receiving one to two hits each day. The project-tracking program is being brought up to speed as Ms. Laura Lampkins takes over as manager to look after data input. Work with regional coordinators and FDA liaison to get RUSTi fully functional is continuing.

Friday May 20th, 2005

LOCATION: Conference Room, Woodfin Suite Hotel, 1380 Piccard Drive, Rockville, MD

WORKING SESSION

ADMINISTRATIVE ADVISORS AND NATIONAL COORDINATOR

The distribution of a LETTER OF INTEREST for a laboratory of method development and analysis of drug residues in the Western Region was discussed. In light of the proposed retirement of Dr. Craigmill as PI in the Western Region, a letter describing the NRSP-7 needs was composed to submit to the Deans and Directors of Western Regional Experiment Stations. A final letter was approved and was to be distributed by the National Coordinator May 23rd. It was agreed that the response period would terminate June 20th, allowing sufficient time for a reply by interested laboratories.

NEW PROJECT PROPOSALS OR WORK FOR NEXT YEAR

NORTHEASTERN – DR. PAUL BOWSER

Continuing projects discussed included INAD 9493 Hydrogen Peroxide as a Therapeutic Compound for Bacterial Gill Disease in Fish; species grouping projects INADs 10-320, 10-823, and 11-145; and Rofenaid in Pheasants INAD 10-804. Additionally, preliminary efforts were noted to establish a minor species project that will focus on the goat industry.

SOUTHERN – DR. ALISTAIR I. WEBB

At this time the Southern Region is considering zolene in partridges, an older ADR in which there has been renewed interest.

WESTERN – DR. ARTHUR L. CRAIGMILL

Discussions have been opened with Pfizer (Dr. Scott Brown) to see if they will support the extension of their label for intramammary ceftiofur to dairy goats. The holdup with Pirlimycin has been the assay, and we already have done the validated milk assay for ceftiofur, so this should be a relatively easy project if they agree to it.

NORTH CENTRAL – DR. RONALD W. GRIFFITH

Developing protocol for lasalocid as a coccidiostat in pheasants.

FALL MEETING

It was decided that the NRSP-7 Fall Meeting 2005 will be held on Oct 3rd & 4th, 2005 at Alpharma in Fort Lee, NJ.

OTHER BUSINESS

There being no other business, the meeting was adjourned

Respectfully submitted:

John G. Babish, Ph.D. Date: 7/9/05
NRSP-7 National Coordinator