NRSP-7

National Research Support Project No. 7

The Minor Use Animal Drug Program

Annual Report

2006

Agricultural Researchers
Pharmaceutical Manufacturers
Animal Producers
USDA
FDA/CVM
Consumers

http://www.nrsp7.org

NRSP-7 Mission Statement

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:

- 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.

To accomplish these goals, NRSP-7 functions through the coordination of efforts among animal producers, pharmaceutical manufacturers, Food and Drug Administration/Center for Veterinary Medicine, United States Department of Agriculture/Cooperative State Research, Education, and Extension Service, universities, State Agricultural Experiment Stations and veterinary medical colleges throughout the country.

Executive Summary

Since the first drug approval in 1984 under the former IR-4 program, NRSP-7 has been responsible for generating 31 Public Master File (PMF) publications in the *Federal Register*, an average of 1.5 per year during its 21 years of funding. Seven data packages have been submitted for review by the Food and Drug Center for Veterinary Medicine. Among those submitted this year were data packages for human food safety/tissue elimination kinetics studies of oxytetracycline in tilapia, walleye, summer flounder, and hybrid striped bass were submission to the Center for Veterinary Medicine for review. Additionally, the Human Food Safety studies of florfenicol for the treatment of respiratory infections in sheep were completed and a final report has been sent to FDA/CVM for review. Tissue stability studies are being conducted as requested by last year's FDA/CVM review of the efficacy and safety study of progesterone implants for estrus synchronization in sheep. Finally, during 2005 the regional coordinators published five articles in peer-reviewed journals containing data developed in the Program.

The mean total expenditure per completed research for a drug approval or publication of a PMF was $430,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $329,000. NRSP-7 continues to demonstrate remarkable efficiency and cost effectiveness. Compared to an average investment of the pharmaceutical industry of $2 to $8 million for adding a label claim to an existing veterinary drug, information generated for additional label claims by the NRPS-7 program costs only approximately 10 to 40% of pharmaceutical industry costs.

To date 341 drug requests have been submitted to the Minor Use Animal Drug Program for the development of data in support of the submission of a New Animal Drug Approval. Currently there are 14 active research projects involving nine animal species and 11 different drugs. Approximately 23% of the active projects involve ruminant species, 15% avian, 38% aquatic and 23% other species such as rabbits and honey bees. While a majority of Public Master Files (53%) involved ruminant species, current active projects are more evenly divided among additional species. Through a prioritization process that has included (i) constraints imposed by concerns of antimicrobial resistance, (ii) limitations of availability of certain expensive or rare animal species, (iii) appropriate efficacy models, and (iv) high risk/benefit liabilities and lack of economic incentive for certain pharmaceutical manufacturers, the number of highest priority projects has been estimated at approximately 41. Added to our 14 current active projects, the backlog of projects represents a research commitment stretching over several decades.

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Project Number: National Research Support Project-7

Project Title: NRSP-7 A National Agricultural Program to Approve Animal Drugs for Minor Species and Uses

Duration: October 1, 2004 – September 30, 2009

Statement of the Problem

In 1976, the Food and Drug Administration (FDA) initiated an extensive study of the minor use of animal drugs through the efforts of a minor use/minor species drug committee. This committee, comprised of representatives of the FDA's then Bureau of Veterinary Medicine and Bureau of Foods, the U.S. Department of Agriculture (USDA), the pharmaceutical industry, and animal producer groups identified the problem as a lack of approved drugs for diseases of minor species and for the principle minor diseases of major species. The committee also identified the principal diseases for which drugs were not available in the minor species. Further, the committee recognized that the livestock industry in the United States relies heavily on the judicious use of drugs for the prevention and treatment of diseases in food animals. Without these drugs, animal suffering and mortality would continue to increase as would the cost of producing animal-derived food products. However, before a drug can be marketed for use in a food animal species, it must be shown to be safe to the human consumer of the animal-derived food, and safe and efficacious in the target animal.

The process of generating the safety and efficacy data necessary for FDA approval of a drug is costly and time-consuming. At present, the estimated cost to a pharmaceutical company for research necessary to obtain FDA approval for a new drug exceeds $20 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $2 to $8 million. Because of this substantial investment in time and resources, pharmaceutical companies must be assured that the drug will have a reasonable potential for profit. Therefore, most drug approvals are sought only for those animal species that are produced in sufficient numbers to support large volume sales, specifically cattle, swine, chickens and turkeys. There is little economic incentive for pharmaceutical firms to generate data necessary to seek FDA approval of drugs in minor species; hence, very few drugs are available for management of diseases in these species. Inequities in drug availability represent serious management and economic problems for producers for minor species.

The FDA was aware that veterinarians and livestock producers were using unapproved drugs without the safeguards that approved drugs carry. Such unapproved drug use could not only cause detrimental effects to the animals being treated, but could also lead to the persistence of drug residues in animal products intended for human consumption. A definite need was identified for approval of minor use veterinary drugs and the scope of the problem was defined. This need was also affirmed by various grower organizations.

In 1982, the IR-4 Animal Drug Program was established as part of the overall IR-4 Minor Use Pesticide Management Program. Since that time the animal portion has established itself as a national means of securing approved drugs and as a conduit between the animal industries and the FDA.

In December 1990, the USDA/CSRS requested a peer review of the IR-4 program, including both the pesticide portion and the minor use animal component. A reorganization of

the minor use animal drug section was one of the recommendations of the Review Team. This Change was carried out with the development of a separate Minor Use Animal Drug Technical Committee that reported to the IR-4 Administrative Advisors.

In 1992, IR-4 Administrative Advisors recommended that with the change from interregional Projects (IR's) to National Research Support Projects (NRSP's), as well as the experience gained under the reorganized IR-4 Project, that the two programs (pesticide and animal) be separated into two projects. In 1993, NRSP-7 was thus created as the Minor Use Animal Drug Program.

Justification and Stakeholders

Gross annual income from production of minor animal species has been estimated by USDA at over $9 billion in the US. Production of aquatic species alone accounts for nearly $1 billion in revenue, much of this isolated in two states. Revenues from processing effectively triple the annual production revenues generated by minor species in the US. While the cumulative contribution of minor species to agricultural income is great, the return to pharmaceutical companies for research on therapeutics for this category is small and generally unprofitable. Since 1964, private sponsors have approved the use of drugs for this need as follows: none for rabbits, one for ducks and pheasants (none for other game birds), two for food fish, four for goats and twenty-one for sheep. Minor and specialty use needs have continued to accumulate, leaving the producers of these species without the drugs necessary for disease prevention and control. More than 41 drug-species combinations are identified as urgently in need of approval for minor species (Table 5). Research at State and Federal Laboratories to provide data necessary for such approval are provided through the Minor Use Animal Drug Program.

The Animal and Plant Health Inspection Service (APHIS) has reported that 9.4% of the lambs born alive died before weaning and that death losses in adult sheep during 1995 were 5.1% of inventory. With 7.8 million sheep and lambs in inventory in 1997, this loss is significant in dollar value. These are but two examples of agricultural losses due to disease and the impact on farm income. There is no total dollar value loss for all minor species as the result of diseases but it has been estimated to be in the billions of dollars. Additionally it should be born in mind the goat industry is growing with the increase in goat-consuming segments of the US population. Despite these acute needs, approval of drugs for use in these animals has been hampered by increased regulatory requirements and spiraling costs of drug development and approval research.

Congress has considered bills to promote drug availability for minor species and for minor uses in major species. The Animal Medicinal Drug Uses Clarification Act of 1994 [AMDUCA] and the Animal Drug Approval Act [ADAA] have expanded "extra label" uses for minor species. Additionally, introduced June 28, 2000 by Mississippi Rep Charles Pickering Jr, the Minor Animal Species Health and Welfare Act [MUMS] was, after considerable effort, passed and signed by President Bush August 2, 2005. This bill established within the FDA/CVM an office supervising an expedited approval process for minor use drugs. The office will also administer grants and contracts to companies producing animal drugs for minor uses. In addition to facilitating new drug development, existing animal drugs could receive conditional approval by the office for minor uses when there is reasonable expectation of efficacy and no human food-safety concerns.

"Minor species" are, by definition, animals other than dogs, cats, horses, cattle, swine, chicken, and turkeys. Included are sheep, deer, rabbits, and aquatic animals. "Minor use" is the use of drugs in minor species, or in any animal species for the control of a disease that occurs infrequently or in limited geographic areas. Amendments to the Internal Revenue Code would allow companies sponsoring drugs for approval to receive a tax credit equal to 50 percent of the clinical testing expenses. Owners of animals submitted for clinical testing could also apply for a tax break. The plan is modeled after the successful Human Orphan Drug Program that has, for the past 20 years, encouraged investment in products to treat rare human diseases.

The limitations imposed by AMDUCA on extra-label drug use in feeds proved to be a major problem to aquaculture and gamebird industries and a guidance document has outlined conditions where limited extra-label use of approved formulations will be permitted under conditions of a valid veterinarian-client-patient relationship. The Minor Use Animal Drug Program is the only organized State/Federal effort to address the inadequate number of FDA approved drugs available for minor-use species and has been responsible for nearly all of the progress made in the approval of minor-use/minor-species drugs.

Federal regulations require an extensive examination of experimental data on efficacy, safety, and residue depletion before any drug can be used in a food animal species. Data must also be obtained for each animal species for which drug use is intended. At present, most minor species of food animals do not have the benefit of the number of safe and effective drugs such as are available for cattle, swine and poultry. This situation has the potential to cause adverse effects upon both the producers and consumers of animal products.

NRSP-7 Objectives

1. Identify the animal drugs for minor species and minor uses in major species.
2. Generate and disseminate data for the safe, effective, and legal use of drugs intended for use in minor animal species.
3. Facilitate FDA/CVM approvals of drugs for minor species and minor uses.

Minor uses include minor species (all species except dogs, cats, horses, cattle, swine, chickens, turkeys) and minor uses in major species are those that occur infrequently or in limited geographical locations. The primary emphasis of The Program is on food-and/or fiber-(hair, wool, fur, feathers or hide) producing minor species with a secondary interest in non-food animals such as bees and tropical fish.

Organization

NRSP-7 is composed of a Technical Committee and four Administrative Advisors representing State Experiment Station Directors. These Administrative Advisors provide liaison between the Directors of the State Experiment Stations, USDA/CSREES, FDA/CVM, various animal organizations, and others coordinating the efforts of this program. The Administrative Advisors provide input on policy, budget and administrative matters.

The organizational structure of the Minor Use Drug program follows:

Administrative Advisory Committee

The Administrative Advisory Committee is composed of one Experiment Station Director from each of the four regions (North Central, Northeast, Southern, and Western). The chair of

the committee is selected internally. The role of the Administrative Advisory Committee is to provide liaison between the Directors of the Agricultural Experiment Stations in the four regions, Colleges of Veterinary Medicine, the USDA/CSREES, the FDA/CVM, various animal organizations, and with those coordinating the efforts of this program. This committee establishes and sets policy consistent with the mission of this project. This committee also advises on budget and administrative matters relating to this program.

Technical Committee

The Technical Committee is composed of the following representatives:

- National Animal Drug Coordinator (Chair)
- Regional Animal Drug Coordinators representing each of the four regions (North Central, Northeast, Southern, and Western)
- Administrative Advisory Committee Chair (non-voting)
- USDA/CSREES Representative (non-voting)
- FDA/CVM liaison to NRSP-7 (non-voting)

In addition to the above committee, the FDA/CVM has a Minor Use Animal Drug Committee that meets with the Technical Committee generally once a year at the semi-annual meetings of the Technical Committee. This FDA committee consists of representatives from the Division of Therapeutic Drugs for Food Animals, Antimicrobial Drugs Branch, Methods Validation and Analytical Branch, Companion and Wildlife Drugs Branch, and the Environmental Sciences Staff. The National Animal Drug Coordinator is salaried on a part-time basis and maintains an office. The Regional Animal Drug Coordinators are not compensated by salary except for secretarial or technical services.

Cooperating Agencies and Principal Leaders:

US Department of Agriculture/CREES

Dr. Gary B. Sherman	USDA/CREES Representative

US Food and Drug Administration/Center for Veterinary Medicine

Dr. Meg R. Oeller	FDA/CVM Liaison

Administrative Advisors

Dr. Garry Adams (Chair)	Texas AES
Dr. Kirklyn M. Kerr	Connecticut AES
Dr. David Thawley	Nevada AES
Dr. John C. Baker	Michigan AES

National Coordinator

Dr. John G. Babish	New York AES

Regional Coordinators

Dr. Arthur L. Craigmill	California AES
Dr. Paul R. Bowser	New York AES
Dr. Alistair I. Webb	Florida AES
Dr. Ronald W. Griffith	Iowa AES

Funding

The Minor Use Animal Drug Program is funded through USDA Special Research Grant, administered by CSREES in cooperation with the NRSP-7 Technical Committee. Currently, there are no "off-the-top" Regional Research funds allocated to the Minor Use Program. The program receives significant "in-kind support from several sources including the institutions conducting the research (State Agriculture Experiment Stations, Colleges of Veterinary Medicine, Federal laboratories), animal producer groups through contributions of animals for research, and pharmaceutical companies. Perhaps the most significant of this "in-kind" support comes through the cooperation of the pharmaceutical companies, which provide access to their proprietary data package prepared for the drug approval in a major species. In addition, the pharmaceutical sponsors complete the approval package by adding the new use of the drug to their current label, and often contribute to the program in the form for drug research, as well as direct financial aid. Without the generous support of the pharmaceutical manufactures, this program would not be possible.

The Regional Animal Coordinators are not compensated by salary for time contributed to the Minor Use Program. In some cases, secretarial and/or technical support services are budgeted from the Program. Funding is provided for the National Drug Coordinator's part-time salary and the maintenance of an office.

The non-federal funds and sources provided for the Minor Use Animal Drug Program were as follows: $156,099 state appropriations, $29,409 industry contributions and $11,365 miscellaneous in 1991; $265,523 state appropriations, $1,182 product sales, $10,805 industry contributions and $59 miscellaneous in 1992; $212,004 state appropriations, $315 industry contributions and $103 miscellaneous in 1993; $157,690 state appropriations and $7,103 miscellaneous in 1994; $84,359 state appropriations in 1995; $191,835 non-federal support in 1996; $357,099 non-federal support in 1997; $104,596 state appropriations and $97,375 industry contributions in 1998; $317,225 state appropriations and $9,678 industry contributions, and $7,000 miscellaneous in 1999; $349,250 state appropriations and $9,500 industry contributions in 2000; $87,000 state appropriations and $38,850 industry contributions in 2001; $137,720 state appropriations and $30,480 industry contributions in 2002; and $82,540 state appropriations, $43,886 industry contributions, and $1200 miscellaneous in 2003; $155,824 state appropriations, and $22,760 industry contributions in 2004; and in 2005 there were $151,962 in state appropriations with $2,360 in industry contributions. Overall, non-federal funding has averaged 39% of federal funding since 1991.

Activities, Accomplishments, Interactions with Stakeholders and Communications

Prior to the Minor Animal Drug Approval Program, the FDA had approved the use of drugs for minor species as follows: none for rabbits, one for ducks and pheasants (none for other game birds), two for food fish, four for goats and twenty-one for sheep. Minor and specialty use needs have continued to accumulate, leaving the producer of these species without the drugs necessary for disease prevention and control. More than 100 drugs have been identified as urgently in need of approval for minor species. The Minor Use Animal Drug Program has received 335 Animal Drug Requests submitted by researcher investigators at federal, state, and university laboratories, veterinarians, and animal industry personnel for approval of a specific drug for the control of a certain disease in an animal industry. Each request is reviewed on basis of need and research is scheduled for selected projects as outlined in Table 1.

Since the first drug approval in 1984 under the former IR-4 program, NRSP-7 has been responsible for generating 31 Public Master File (PMF) publications in the *Federal Register*, an average of 1.5 per year during its 21 years of funding (Table 2). The mean total expenditure per completed research for a drug approval or publication of a PMF was $430,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $329,000. NRSP-7 continues to demonstrate remarkable efficiency and cost effectiveness. Compared to an average investment of the pharmaceutical industry of $2 to $8 million for adding a label claim to an existing veterinary drug, information generated for additional label claims by the NRPS-7 program costs only approximately 10 to 40% of pharmaceutical industry costs.

Currently there are 14 active research projects involving nine animal species and 11 different drugs (Table 3). Approximately 23% of the active projects involve ruminant species, 15% avian, 38% aquatic and 23% other species such as rabbits and honey bees. While a majority of Public Master Files (53%) involved ruminant species, current active projects are more evenly divided among additional species. Through a prioritization process that has included (i) constraints imposed by concerns of antimicrobial resistance, (ii) limitations of availability of certain expensive or rare animal species, (iii) appropriate efficacy models, and (iv) high risk/benefit liabilities and lack of economic incentive for certain pharmaceutical manufacturers, the number of highest priority projects has been estimated at approximately 41. Added to our 14 current active projects, the backlog of projects represents a research commitment stretching over several decades. (Table 4).

Objective 1

Identify the critical needs of the various producers of minor livestock species

The Southern Region has taken responsibility for the NRSP-7 Home-Page [www.nrsp-7.org]. This resulted in reworking the public sector and, the IP limited access site ["Ringer Site"] which continues to allow members of the committee access to archival data, relevant media material, and information on on-going projects. The latter includes an ASP interactive database ["MUMS Rx"], which will complete development in the current year and be available for public access.

During the last four years, drug coordinators, the USDA representative and the FDA liaison have conducted regular teleconferences. These have been coordinated by the PI of the Southern Region and have proved very successful in facilitating communication and coordination between the parties participating. These teleconferences usually take place at 1100 hours EST on the first Monday of the month.

Objectives 2 and 3

Generate and disseminate data for the safe, effective, and legal use of drugs used primarily in therapy or reproductive management of minor animal species.
Facilitate FDA/CVM approvals of drugs for minor species and minor uses.

Seven data packages have been submitted for review by the Food and Drug Center for Veterinary Medicine. The data packages for human food safety/tissue elimination kinetics studies of oxytetracycline in tilapia, walleye, summer flounder, and hybrid striped bass were submission to the Center for Veterinary Medicine for review. The Human Food Safety studies of florfenicol for the treatment of respiratory infections in sheep were completed and a final report

has been sent to FDA/CVM for review. Tissue stability studies are being conducted as requested by FDA/CVM review of efficacy and safety study of progesterone implants for estrus synchronization in sheep. Finally, the regional coordinators published five articles in peer-reviewed journals containing data developed in the Program.

To date 341 drug requests have been submitted to the Minor Use Animal Drug Program for the development of data in support of the submission of a New Animal Drug Approval. Through a prioritization process that has included (i) constraints imposed by concerns of antimicrobial resistance, (ii) limitations of availability of certain expensive or rare animal species, (iii) appropriate efficacy models, and (iv) high risk/benefit liabilities and lack of economic incentive for certain pharmaceutical manufacturers, the number of highest priority projects has been estimated at approximately 41 (Table 4). Added to our 14 current active projects (Table 3), the backlog of projects represents a research commitment stretching over several decades.

Summary of Current Projects and Publications

The data packages for human food safety/tissue elimination kinetics studies of oxytetracycline in tilapia, walleye, summer flounder, and hybrid striped bass were submission to the Center for Veterinary Medicine for review. The Human Food Safety studies of florfenicol for the treatment of respiratory infections in sheep were completed and a final report has been sent to FDA/CVM for review. Tissue stability studies are being conducted as requested by FDA/CVM review of efficacy and safety study of progesterone implants for estrus synchronization in sheep. Finally, the regional coordinators published 5 articles in peer-reviewed journals containing data developed in the Program.

PROGRAM ACTIVITY BY REGION

NORTHEAST REGION

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.

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 sponsor (Alpharma Animal Health) has developed a means of circumventing the palatability problem with this therapeutant. In a recent development, Alpharma sold all of its aquaculture products to PHARMAQ, a company specializing in health products for the aquaculture industry. We anticipate performing human food safety trials in hybrid striped bass 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.

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) and hybrid striped bass (20C, 25C). All tissues samples for tilapia and walleyes have been analyzed. Samples from hybrid striped bass are being analyzed.

Rofenaid in pheasants. (INAD 10-804)

A Target Animal Safety study of Rofenaid in Pheasants has been completed. Currently, statistical analyses is underway for the data describing body weight, body weight gain, feed consumption and feed efficiency. Small differences were observed in weight gain at the end of the experimental period (28 days), in favor of the groups fed Rofenaid at 5X the normal concentration. A problem was encountered with background lesions in the population of birds used for the study. As a result, the Target Animal Safety Study will be repeated. Birds will be obtained from a different source and grown under laboratory conditions until they are used. We believe this will eliminate the problem encountered in the initial trial.

NORTH CENTRAL REGION

CIDR-g for Sheep. The North Central Region of NRSP-7 is currently working with Dr. Dennis Hallford at New Mexico State University, Las Cruces, NM on completing the tissue residue studies required for supporting approval of the CIDR-g progesterone intravaginal sponge for use in ewes. Problems were encountered with this study when the stability of progesterone in frozen tissues was challenged by the CVM reviewer. Other studies have indicated that progesterone is very stable in frozen tissues but the reviewer of the data package at CVM is requiring a separate stability study. Alternatively, it may be simpler to repeat a portion of this study (12-day treatment) and avoid a 6-month delay in determining stability. In addition, we are attempting to document the fact that progesterone is very stable in frozen tissues by reference which would avoid the need for any further experimental work in sheep.

Aquaflor in Shrimp. The North Central Region supported the work of Dr. Delbert Harris at Iowa State University to determine the efficacy of Aquaflor (florfenicol) against necrotizing hepatopancreatitis in shrimp. This study was terminated in 2005 because the florfenicol was leaching from the pelleted shrimp rations and the animals were not receiving sufficient levels of the drug to adequately determine efficacy. Similar pelleted rations had worked well for other aquaculture species but the feeding habits of shrimp allowed too much time for the drug to leach out. Schering-Plough Animal Health may decide to alter the formulation for shrimp diets. If that occurs a decision will be made whether to re-instate funding for the project.

Nuflor in Veal Calves. The status of veal calves as a minor use in a major species was challenged in 2004 and work on this project was terminated as a result. Studies on the pharmacokinetics of Nuflor in veal calves have been completed and the project is in the data analysis phase in the Western Region laboratory. Nuflor (florfenicol) is approved for use in cattle and NRSP-7 has performed some of the studies necessary for approval in sheep. The status of veal calves as a minor use is currently under review. If the FDA/CVM designates veal calves as distinct from cattle, then we may re-initiate the TAS and Tissue Residue studies.

Lasalocid in Pheasants. A product development meeting is being scheduled for determining the data required for approval of lasalocid for use against coccidiosis in ring-necked pheasants. This project has been held up while awaiting information concerning the

manufacturer's data package submitted in Europe. This information was only recently received and the project can now go forward.

SPECIFIC PROJECTS PROPOSED FOR 2006-2008

CIDR-g in Goats. This project is being done in cooperation with the Western Region of NRSP-7. The North Central Region will provide financial and logistical support for the Tissue Residue studies being performed by Dr. Dennis Hallford at New Mexico State University, Las Cruces, NM. The Western Region will provide QA/QC support and overall direction for the study. Currently, Dr. Hallford is verifying the in-vitro extraction and analysis necessary prior to the start of the study.

Tulathromycin in Sheep and Goats. An animal drug request was processed to perform the necessary studies to support approval for Tulathromycin (Draxxin) in both sheep and goats. Draxxin is a long-acting macrolide antimicrobial that has been approved for use in cattle and swine. The advantages of this drug are: a. It has excellent activity against some of the major pathogens of sheep and goats and, b. It is administered as a single subcutaneous injection that provides effective tissue antimicrobial levels for up to eight days. Given the recent nature of ADR (animal drug request) the protocols for the required studies are under development and will be presented to the Office of New Animal Drug Evaluation (ONADE) as soon as possible. The proposed studies will include a validation of the Efficacy (including pharmacokinetics), Target Animal Safety, Tissue Residues, and Environmental Assessment. These studies will need to be performed independently for both sheep and goats as outlined briefly below:

Draxxin Efficacy: This study involves two components**: A. Verification of the in-vitro antimicrobial susceptibility of sheep and goat pathogens to Draxxin.** This will involve collection of numerous isolates of *Mannheimia haemolytica, Pasteurella multocida,* and possibly *Mycoplasma ovipneumoniae* from different areas of the U.S. The collection of these isolates is already underway in cooperation with the Iowa State University Veterinary Diagnostic Laboratory and the Texas A&M State Diagnostic Laboratory. Once assembled, the in-vitro susceptibility of these isolates to Draxxin will be evaluated. **B. Determination of the pharmacokinetics of Draxxin.** Eight normal animals of each species will be injected subcutaneously with Draxxin and blood samples taken at -60, 15 and 30 minutes and 1, 3, 6, 12, 18, 24, 48, 72, 96, and 120 hours. The serum samples will be analyzed for Draxxin levels at each time point and the results bridged to the values published for Draxxin in cattle.

Draxxin Target Animal Safety: Six normal animals of each species (3 males and 3 females) will be injected subcutaneously with Draxxin at 1-, 3- and 5X times the recommended dose given for 3 times the normal duration. An opinion on whether a 10X dose will be required is being sought from reviewers at FDA/CVM. The sheep and goats will be monitored for adverse clinical effects and, at the termination of the study, will be carefully necropsied and examined for gross and histopathologic lesions.

Draxxin Tissue Residue: Twelve normal animals of each species (6 males and 6 females of each species) will be used for this study. Half of the animals will serve as untreated controls. The other six animals will be injected subcutaneously with Draxxin at the proposed label dose (2.5mg/kg body weight). All animals will be euthanized approximately 18 days following injection (as determined by the results of the pharmacokinetic studies). Liver and muscle tissue samples will be removed from each animal. The tissues will be processed and analyzed for residual levels of Draxxin.

Draxxin Environmental Impact: It is likely that this will be done by reference to the studies performed for both cattle and swine and new experimental data will not be required.

Regulin. Regulin is formulated as an implant of melatonin injected subcutaneously in the ear of ewes to induce early estrus. The implants are currently licensed and used mainly in Europe and Australia. Sheep are seasonally polyestrus and producers routinely have to wait until late August to September at the earliest to breed ewes. Even then, early breeding can result in lower fertility. This means that ewes spend much of the year not pregnant and not nursing lambs. Regulin provides an important means to extend the breeding season of sheep and thereby increase their productivity. Regulin is produced by CEVA in France and this company has generated significant amounts of data supporting approval in Europe and Australia under GLP and GCP standards. This data will need to be reviewed by ONADE. It is likely that some type of efficacy study will need to be performed in the U.S., but other components of the data package may be acceptable for approval in the U.S.

SOUTHERN REGION

Over the past year the coordinators of the Southern and Western regions, together with the FDA Liaison, worked to complete preparation of the proceedings of the International Workshop on Minor Use and Minor Species (MUMS): A Global Perspective. This had been held in Rockville, Maryland October 7th and 8th 2004 and featured 14 speakers from 8 countries. It has been very positively received and overseas participants conceded that the USA was ahead of them in working for drug approvals for minor species./ minor uses in major species.

It is disappointing that, although all in-life work has been completed for the tissue depletion and target animal safety [TAS] work for the fenbendazole in gamebirds approval [ADR 280 INAD 10-062] that final reports are still incomplete. In the case of the TAS the report is having to be re-written. The *in vivo* work of repeating the ivermectin human food residues studies in rabbits [ADR 107/141] has been completed and the tissue assays are now in progress. The Southern Region was able to use this duplication in the training of the newly hired biological scientist and chemist. Both the *in vivo* and the analytic sections received favorable GLP review. At FDA's suggestion we are cross validating the ivermectin method with beef tissues as that was the species that the method was originally developed for. These is also the possibility that the human safety study of ivermectin pour-on with bison [ADR 125, Central Region] may be completed now the Southern Region has a successful assay mounted and going.

Although it is classed as a production drug, [aid in spawning], the administrative work and funding for the target animal safety study for crude carp pituitary extract has been handled by the Southern Region. The target animal safety study was completed and a report submitted to FDA. Unfortunately FDA have indicated that problems with the study preclude it being accepted by the agency. Negotiations have just started to see if it is practical or the wish of the NRSP-7 program to repeat these studies. This decision is complicated by the fact that it seems likely that no manufacturer will be willing to take this further citing FDA Good Manufacturing Practices [GMP] audit problems.

Intervet and the Southern Region are collaborating on conducting studies in support of an approval for fenbendazole in deer. A possible collaborator has been identified for the target animal safety and a product conference with FDA and the sponsor has been held to determine

requirements for a claim in white tailed deer. At the conference NRSP-7 made it clear that a claim for all deer or cervidae is the ultimate desire.

Following the Fall NRSP-7 meeting held at Alpharma's New Jersey site the decision was made to reactivate the studies of lasalocid [a coccidiostat] in non-lactating goats and farmed deer. A teleconference with FDA and the sponsor has clarified the requirements for approvals. The big problem is that the sponsor does not want to proceed if there is not a zero withdrawal time in those animals. This makes the human safety the first priority. To this end, work is proceeding on mounting the regulatory assay for lasalocid. The Efficacy Protocol has been reviewed by FDA/CVM and has undergone revision for re-submission.

The Staff of the Southern Region represented NRSP-7 at the North American Veterinary Conference in Orlando early this year in addition to providing logistic support for the NRSP-7 representations at the American Veterinary Medical Association [AVMA] and the Association of Bovine Veterinary Practitioners [ABVP].

The Southern Region continues being responsible for the NRSP-7 Home-Page [www.nrsp-7.org] and the IP limited access site ["Ringer Site"] which continues to allow members of the committee access to archival data, relevant media material, and information on on-going projects. The latter includes an ASP interactive database ["MUMS Rx"] which was developed with the Food Animal Residue Avoidance Databank [FARAD] and which is available for public access. Work is completed in developing an interactive project tracking system [Regional Update Status Tracking Infobase – RUSTi] and we are working with all regional coordinators to populate the database. The prototype was praised during the program review conducted by a CSREES appointed team. RUSTi is mounted on the Ringer site.

During the last several years the drug coordinators, USDA program director and the FDA liaison conducted regular teleconferences. These have been coordinated by the PI of the Southern Region and continued to be very successful in facilitating communication and coordination between the parties participating. It is now common that some of the administrative advisors join the conference as well. These conference usually take place at 1130 hours EST on the first Monday of the month .

CURRENT PROJECTS

Ivermectin & Rabbits: The TAS and human safety studies are all that remain for a complete approval packet with only the tissue analysis as described above being the only outstanding issue holding developments of final reports.

Deer Drug Studies: These are for fenbendazole and lasalocid and are discussed above. The non-domesticated nature of these animals makes *in vivo* studies problematic. It was a positive step that in both product conferences FDA acknowledged that and suggested use of immature animals [and most vulnerable] in the efficacy and TAS work. The human safety would still require adult animals of marketable weight. Both studies would try to incorporate white tailed, red and fallow deer. FDA indicated that an approval of these three species would create a "all deer" label.

Goat Drug Studies: The same applies for goat studies as for deer as it is intended to use identical protocols.

Crude Carp Pituitary: The problem with FDA's review of the target animal safety studies has been discussed above. It is hoped that this will be resolved shortly. Another problem that remains is the manufacturer's withdrawal because of GMP problems so a new sponsor is being

sought. If this is unsuccessful the FDA may be asked to accept data from the PMF and consider the preparation to be of low regulatory concern.

Gamebird Drug Studies: With regard to the fenbendazole studies, only the target animal safety and human safety remain. Both are moving towards conclusion and reports are expected soon. The zoalene (coccidiosis) and nitarsone (trichomoniasis in partridge) have been closed and passed onto the Western Region where they have the ability to mount an efficacy study

Web Site Development: The web site for NRSP-7 is managed from the University of Florida. We have had over a thousand visits the past year. Most of these also visited the interactive database for drugs approved for minor species [MUMSRx]. This uses data made available from the Food Animal Residue Databank [FARAD] with which we share computer facilities and a programmer. The reaction continues to be very enthusiastic. The Southern Region also maintains the password/IP restricted site (Ringer Site) for the project members to share data and protocols. RUSTi, the project tracking system is mounted there.

Work Planned for the Coming Period: The top priority is to complete and submit reports for ivermectin/rabbits and fenbendazole/gamebirds. After that is to get the studies for deer and goats established. These represent tasks already commenced. We will continue to 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.

WESTERN REGION

During 2005, the primary accomplishments were:

- **Florfenicol in Sheep for respiratory disease (ADR #325):** The MIC technical report is complete and has been sent to the Food and Drug Administration/Center for Veterinary Medicine (FDA/CVM) for review. The method validation report and the human food safety portion are both under QA review.
- P**rogesterone CIDRs in Sheep for estrous synchronization (ADR #258)**: The target animal safety portion was completed and the final report has been accepted by FDA/CVM.
- **Progesterone CIDRs in Goats for estrous synchronization (ADR #324):** The Target Animal Safety study was completed in September 2005. The Technical Report is under preparation. The milk residue and human food safety studies are being planned for 2006.
- **Tylosin in Bees to control American foulbrood disease (ADR #217)**: FDA approved Tylan Soluble (tylosin) for the control of American Foulbrood in Honey Bees, October 20, 2005.
- **Romet-30 in Fish for bacterial infections (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**.**
- **Florfenicol in Fish for bacterial infection (ADR #334)** (collaborative project with the Northeast Region). Our laboratory has processed over 900 samples this year.

- **Species Grouping**: The work on the *in vitro* studies has been completed. A paper on the first portion of the *in vitro* modeling has been accepted for publication in the *Journal of Veterinary Pharmacology and Therapeutics*. The PBPK model for the birds will be accomplished during the summer of 2006. Whole animal studies have been run in all species for serum pharmacokinetics of midazolam, the CYP3 marker substrate.

The findings from all of these studies will be utilized to fulfill the data requirements for the FDA/CVM approval of drugs for use in minor species.

WORK PLANNED FOR NEXT YEAR

The completion of the projects above is the primary work planned for next year, together with continued research on species grouping for avian species. All of these findings have been or will be used to gain FDA/CVM approval of these drugs for use in the respective minor species, which will be of great benefit to producers and veterinarians.

PROJECTS CLEARED

ADR# 8 Albendazole for treatment of adult liver flukes in non-lactating goats. (Washington, California)
ADR #11 Ivermectin for treatment of warbles in reindeer. (Alaska, California)
ADR #87 Amoxicillin for treatment of bacterial pneumonia in sheep. (Idaho, California)
ADR #111 Decoquinate for treatment of coccidiosis in goats. (Washington, California)
ADR #127 Fenbendazole for treatment of lungworms in bighorn sheep. (Washington, California)
ADR #169 Formalin for the treatment of protozoal infections of marine penaeid shrimp. (Arizona, California)
ADR #170 Naxcel® Sterile Powder (Ceftiofur) for the treatment of respiratory disease in sheep. (California)
ADR #171 Naxcel® Sterile Powder (Ceftiofur) for treatment of bacterial pneumonia in goats. (California, Idaho)
ADR #217 Tylosin for the treatment of foulbrood disease in bees. (California)

RESEARCH COMPLETED--PUBLIC MASTER FILES IN PREPARATION

ADR #135 Erythromycin to treat bacterial kidney disease in salmonids. (Idaho, California)
ADR #176 Amoxicillin for use in lactating dairy goats. This project is combined with ADR #33 to cover lactating goats. Milk residue study completed and submitted to FDA/CVM. (California)

COMPLETED PROJECTS

ADR #43 Oxytetracycline for the treatment of respiratory disease in goats. The efficacy and target animal safety studies are completed. A milk residue depletion study was conducted in 1999 and the report was submitted to CVM February 2000. A paper on the pharmacokinetics and residues in meat and milk was published in the *Journal of Veterinary Pharmacology and Therapeutics,* 25(25-32), 2002. (California, Idaho, New York)
ADR #83 Oxytetracycline to treat respiratory disease in sheep. The results of this research have been published in the *Journal of Veterinary Pharmacology and Therapeutics*, 23(345-352), 2000.
ADR #199 Enrofloxacin for the treatment of vibriosis in shrimp. The data needed by the investigator for the final report were received in 1994, however the final report

was not acceptable and was never addressed by the investigator. (Arizona, California)

ADR #222 Ivermectin Pour-On for the treatment of gastrointestinal parasites in American bison. Our laboratory has completed the serum and tissue residue analyses and these results were added to the final report and submitted in 1999. The Human Food Safety and Target Animal Safety technical reports were submitted to CVM in August 1999 and CVM responded in July 2000 requesting more information. A follow-up freezer stability study should be completed this year. (California, Michigan)

ADR #251 Ceftiofur for the treatment of respiratory diseases in red deer. Publication of "Pharmacokinetics of Ceftiofur in Red Deer" has been published in the *Journal of Veterinary Pharmacology and Therapeutics,* 27(1)13-20, 2004.

ADR #261 Ceftiofur for the treatment of respiratory diseases for psittacine birds. Pharmacia & Upjohn, Inc. have provided funding for this project. (Preliminary studies have shown equivalent levels in serum to other species (sheep) but more rapid elimination.) The research has resulted in a publication (*Journal of Veterinary Pharmacology and Therapeutics,* 21(85-91), 1998, however despite support from the sponsor for the study, they will not support further work to add psittacines to the product label, thus this project is complete.

ADR #275 Ceftiofur sodium (Naxcel®) for the treatment of respiratory infections in llamas and alpacas. Publication of "Pharmacokinetics of Ceftiofur in Llamas and Alpacas" has been published in the *Journal of Veterinary Pharmacology and Therapeutics,* 27(1)7-11, 2004. The project was only partially funded by the NRSP-7 project. (Collaborative project with the Southern Region)

ADR #284 MGAGnRH for estrus synchronization and out-of-season breeding in sheep. Our laboratory director provided GLP assistance for this project in March of 1998. A preliminary report from Idaho indicates that the researcher was not able to show that MGA induced out-of-season breeding. (Idaho/California)

ADR #325 Florfenicol for respiratory disease in sheep. The MIC technical report is complete and has been sent to FDA/CVM for review. The method validation report and the human food safety portion are both under QA review.

ACTIVE PROJECTS

ADR #107 Ivermectin to treat ear mites in rabbits. Analysis was postponed due to continuing difficulties with recovery and interfering peaks. The tissue residue samples are more than two years old and will need to be redone and will be analyzed by the southern region. (Florida, California)

ADR #258 Progesterone CIDRs for sheep. The target animal safety portion was completed and the final report has been accepted by FDA/CVM.

ADR #270 Amoxicillin for the treatment of respiratory diseases in striped bass. While this project remains on the active list for the region, there has been no activity to report for the last year. (California)

ADR #280 Fenbendazole for the treatment of gastrointestinal parasites in game birds. (Collaborative project with the Southern Region): Method validation has been completed and the final report was submitted to FDA/CVM for review and accepted. Results of the tissue residue analysis have been provided to the Southern Region Coordinator for inclusion in the technical report package submission to CVM.

ADR #295 Strontium chloride for use as a marking agent in salmonids. The investigator has been contacted and is in the process of assembling a report on project activities. There has been no further activity on this project. (California/Alaska)

ADR #299 Pirlimycin to treat mastitis in dairy goats. This project is still in the works but little progress has been made in the past year. This project is likely to be replaced by a project on another mastitis formulation recently approved by the CVM and of potentially greater usefulness. (California)

ADR #311 Lincomycin to treat American Foulbrood in honey bees. The target animal safety report was accepted by FDA/CVM.

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

ADR #324 CIDR in Goats. The target animal safety study was completed in September 2005 and the technical report is under preparation. The milk residue and human food safety studies are being planned for 2006.

ADR #334 Florfenicicol in fish. (Collaborative project with the North East Region) Our laboratory has processed over 900 samples during 2005.

POTENTIAL FUTURE PROJECTS

ADR #302 Various antibiotics to treat bacterial infections in shellfish. (California, Washington)

Continuation projects and new projects will be considered at the Minor Use Animal Drug Spring Meeting in 2006.

The completion of the Minor Use Animal Drug projects mentioned above entail intensive sample collections and sample analyses. Analytical method implementation and validation must be done for each drug for each species. Thousands of serum and tissue samples were analyzed by High Performance Liquid Chromatography (HPLC) for the florfenicol project alone. These HPLC analyses were labor intensive and expensive, however, the data generated under GLP's will satisfy the FDA/CVM requirements.

Progress on all projects undertaken is slow, but steady, and the number of projects completed stands as proof to the effectiveness of the program.

NRSP-7 Publications in 2005

Chen, C.-Y. and P.R. Bowser. 2005. Pharmacokinetics of oxytetracycline in Nile tilapia (*Oreochromis niloticus*)challenged with Streptococcus iniae and *Vibrio vulnificus*. Journal of the World Aquaculture Society 36(3):262-270.

Chen, C.-Y., G.A. Wooster, R.G. Getchell and P.R. Bowser. 2005. Distribution and depletion of oxytetracycline in two warm-water fish: tilapia and hybrid striped bass. Journal of the World Aquaculture Society 36(4):564-569.

Bowser, P.R., N. Abou-Madi, M.M. Garner, S.L. Bartlett, S.G. Grimmett, G.A. Wooster, T.A. Paul, R.N. Casey and J.W. Casey. 2005. Fibrosarcoma in yellow perch (Perca flavescens). Journal of Fish Diseases 28: 1-5.

Getchell, R.G., W.J. Culligan, M. Kirchgessner, C.A.Sutton, R.N. Casey and P.R. Bowser. 2005. Quantitative PCR Assay to Measure the Prevalence of *Clostridium botulinum* type E In Fish in the Lower Great Lakes. Journal of Aquatic Animal Health 18:39-50.

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*). 18:39-50.

Submitted:

John G. Babish, Ph.D. National Coordinator Chair, Technical Committee	Date
L. Garry Adams, DVM, Ph.D. Chair, Administrative Advisors	Date

Table 1. Operation of NRSP-7 Following the Identification of Need Through Research, FDA/CVM Submission and Drug Approval

I **Drug Request/Need Identified**	II **Fund or Conduct Research**	III **Submit Data Package to FDA/CVM**	IV **FDA/CVM Review, Publication of Public Master File and New Label Claim**
1. An animal drug request is filed with the one of the four Regional Animal Drug Coordinators or the National Coordinator.	4. Send to the Regional Animal Drug Coordinator to initiate work with an investigator.	9. Prepare study report for FDA (investigator with assistance from the Regional Animal Drug Coordinator).	12. FDA/CVM prepares Public Master File containing summaries of the study reports.
2. Informal review by FDA/Center for Veterinary Medicine (CVM) and the drug company to identify current information available relative to the drug and any major clearance problems.	5. Develop and send protocols to FDA/CVM and the drug company for review.	10. Regional Animal Drug Coordinator sends a draft copy of the study report to the drug company for review. Also sends copy to the FDA liaison to the NRSP-7 project for informal review.	13. FDA/CVM formally reviews the Public Master File.
3. Approval of new projects by the Animal Drug Technical Committee.	6. Provide funding to the investigator to initiate studies.	11. Regional Animal Drug Coordinator finalizes report and submits it to FDA/CVM.	14. FDA/CVM publishes the Public Master File in the *Federal Register*.
	7. Conduct studies under Good Laboratory Practices (GLPs): 1. Efficacy 2. Target animal safety 3. Human food safety 4. Environmental safety		15. Pharmaceutical company references the Public Master File and adds claim to existing label.
	8. Prepare Environmental Impact Assessment Statements.		

Table 2. Public Master Files (PMF) Published and New Animal Drug Approvals (NADA)

Drug	Formulation	Species	Indication	Group	Status
Albendazole†	Oral suspension	Goats	Liver flukes	Ruminant	PMF
Amoxicillin trihydrate†	Injectable	Sheep	Bacterial pneumonia	Ruminant	PMF
Amprolium	Premix	Pheasants	Coccidiosis	Avian	Approved
Bacitracin	Premix	Quail	Ulcerative enteritis	Avian	Approved
Ceftiofur	Injectable	Goats	Bacterial pneumonia	Ruminant	Approved
Ceftiofur	Injectable	Sheep	Bacterial pneumonia	Ruminant	Approved
Clorsulon†	Oral suspension	Goats	Liver flukes	Ruminant	PMF
Decoquinate	Premix	Goats	Coccidiosis	Ruminant	Approved
Decoquinate	Premix	Sheep	Coccidiosis	Ruminant	Approved
Fenbendazole	Premix	Bighorn sheep	Lungworms	Ruminant	Approved
Fenbendazole	Oral suspension	Goats	GI parasites	Ruminant	Approved
Formalin	Topical soluble powder	Finfish and eggs	External fungal & protozoan parasites	Aquatic	Approved
Formalin	Oral soluble powder	Penaeid shrimp	External protozoan parasites	Aquatic	Approved
Ivermectin	Injectable	American bison	Hypodermosis	Ruminant	Approved
Ivermectin	Injectable	Fox	Ear mites	Other	Approved
Ivermectin†	Injectable	Goats	GI parasites	Ruminant	PMF
Ivermectin	Injectable	Reindeer	Warbles	Ruminant	Approved
Lasalocid	Premix	Chukar partridges	Coccidiosis	Avian	Approved
Lasalocid	Premix	Rabbits	Coccidiosis	Other	Approved
Levamisole†	Oral soluble powder	Goats	G.I. parasites	Ruminant	PMF
Monensin	Premix	Goats	Coccidiosis	Ruminant	Approved
Monensin	Premix	Quail	Coccidiosis	Avian	Approved
Morantel tartrate	Premix	Goats	GI parasites	Ruminant	Approved
Oxytetracycline	Premix	Lobster	Gaffkemia	Aquatic	Approved
Oxytetracycline	Immersion	Various fish	Otolith marking	Aquatic	Approved
Salinomycin	Premix	Quail	Coccidiosis	Avian	Approved
Sulfadimethoxine /ormetoprim	Premix	Catfish	Bacterial infections	Aquatic	Approved
Sulfadimethoxine /ormetoprim	Premix	Chukar partridges	Coccidiosis	Avian	Approved
Thiabendazole	Premix	Pheasants	Gapeworm	Avian	Approved
Tilmicosin phosphate	Injectable	Sheep	Chronic respiratory	Ruminant	Approved
Tylosin	Soluble powder	Honey bees	Foul brood	Other	Approved

†Public Master File

Table 3. NRSP-7 Active Projects

Drug	Formulation	Species	Indication
Carp pituitary	Injectable	Various fish	Spawning aid
Erythromycin	Premix	Salmonids	Bacterial kidney disease
Fenbendazole	Premix	Pheasants	Gapeworm & capillaria
Florfenicol	Oral	Shrimp	Necrotizing pancreatitis
Florfenicol	Oral	Finfish	Bacterial infections
Florfenicol	Injectable	Sheep	Respiratory infections
Ivermectin	Injectable	Rabbit	Ear mites
Lincomycin	Soluble powder	Bees	American Foulbrood
Oxytetracycline	Feed	Various fish	Vibriosis
Pirlimycin	Intramammary	Goats	Mastitis
Progesterone	CIDR	Sheep	Estrus synchroization
Strontium chloride	Immersion	Various fish	Otolith marking
Sulfadimethoxine & ormetoprim	Premix	Pheasants	Bacterial infections & coccidiosis
Sulfadimethoxine & ormetoprim	Premix	Various fish	Bacterial infections

Table 4. Potential NRSP-7 Projects

Drug	Formulation	Species	Indication
Amoxicillin	Premix	Salmonids	Furunculosis
Amoxicillin	Premix	Hybrid striped bass	Strep infections
Amoxicillin	Injectable	Dairy goats(lactating)	Bacterial pneumonia
Ceftiofur	Injectable	Rabbits	Pasteurellosis
Ceftiofur	Injectable	Red deer	Respiratory infections
CIDR	Intravaginal	Goats	Estrus synchronization
Clopidol	Premix	Pheasant	Coccidiosis
Copper sulfate	Topical soluble powder	Channel catfish	External protozoa
Deccox	Premix	Pheasants	Coccidiosis
Deccox	Premix	Partridges	Coccidiosis
Erythromycin	Premix/ injectable	Salmonids	Bacterial kidney disease
Fenbendazole	Premix	Fallow deer	GI parasites
Florfenicol	Injectable	Sheep	Foot rot
Florfenicol	Injectable	Goats	Respiratory infections
Florfenicol	Injectable	Goats	Foot rot
Florfenicol	Oral	Shrimp	Necrotizing pancreatitis
Hydrogen peroxide	Topical	Atlantic salmon	Sea lice
Ivermectin	Pour-on	Red deer	GI parasites and lungworm
Ivermectin	Pour-on	American bison	GI parasites
Ivermectin	Injectable	Emu	Nematodes, lice, mites
Lasalocid	Premix	Pheasant	Coccidiosis
Lasalocid	Premix	Deer	Coccidiosis
Lasalocid	Oral	Goats	Coccidiosis
MGA/GnRH	Feed/injectable	Sheep	Estrus synchronization
Monensin sodium	Premix	Pheasants	Coccidiosis
Monensin sodium	Premix	Partridges	Coccidiosis
Nitarsone	Premix	Partridge	Blackhead
Novobiocin/ penicillin	Intramammary infusion	Dairy goats	Mastitis
Oxytetracycline	Premix	Alligators	Bacterial infection
Oxytetracycline	Injectable	Dairy goats (nonlactating)	Bacterial pneumonia
Oxytetracycline	Injectable	Sheep	Bacterial pneumonia
Oxytetracycline	Oral	Abalone	Withering syndrome
Pirlimycin	Intramammary	Goats	Mastitis
Potassium permanganate	Topical	Catfish	External ichthyophthirius multifilis
Praziquantel	Premix/oral capsule	Wild ducks	Schistosomiasis
Praziquantel	Premix/oral capsule	Geese	Schistosomiasis
Praziquantel	Premix/oral capsule	Mute swan	Schistosomiasis
Spectinomycin	Injectable/oral soluble powder	Ducks	Colibacillosis, salmonellosis
Sulfadimethoxine/ormetoprim	Premix	Pheasants	Bacterial infection & coccidiosis
Sulfamethazine	Oral sustained release tablets	Sheep	Bacterial pneumonia
Zoamix	Premix	Pheasants	Coccidiosis

Appendix I
Animal Drug Requests Received by NRSP-7 through 2005

NRSP-7 MINOR USE ANIMAL DRUG PROGRAM: ANIMAL DRUG REQUESTS

ADR	Date rec'd	Drug	Formulation	Species	Indication	Firm	Reg	Status
1	Feb-82	Monensin	premix	goats	coccidiosis	Elanco	S	Approved
2	Apr-82	Amprolium	premix	pheasants	coccidiosis	Merial	NE	Approved
3	Nov-81	Monensin	premix	sheep	coccidiosis	Elanco	NC	z-No Proj
4	Jun-82	Sulfadimethoxine/ ormetoprim	premix	catfish	bacterial infections	Alpharma	S	z-Dup
5	Apr-84	Thiabendazole	premix	pheasants	gapeworm	Merial	NE	Approved
6	Nov-82	BHT	premix/ unspecified topical	fish	viral diseases	——	W	z-No Proj
7	Oct-82	Various coccidiostats & antibiotics	——	rabbits	coccidiosis, pasteurellosis	——	HQ	z-No Proj
8	Dec-82	Albendazole	oral suspension	goats	liver flukes	Pfizer	W	PMF
9	Dec-82	Lincomycin	premix	ducks	pasteurellosis	Pharmacia	NE	z-No Proj
10	Dec-82	Penicillin	premix	ducks	erysipelas	Fort Dodge	NE	z-No Proj
11	Sep-81	Ivermectin	injectable	reindeer	warbles	Merial	W	Approved
12	Jul-83	Fenbendazole	oral suspension/ premix	goats	GI parasites	Intervet	NC	z-No Proj
13	Jan-83	Monensin	premix	cattle	emphysema	Elanco	HQ	z-No Proj
14	Jan-83	Decoquinate	premix	sheep	coccidiosis	Alpharma	S	Approved
15	Oct-83	Oxytetracycline	premix	lobster	gaffkemia	Phibro	NE	Approved
16	Feb-83	Xylazine	injectable	goats	anesthesia	Bayer	NC	z-No Proj
17	Jan-83	Ivermectin	injectable	goats	GI parasites	Merial		PMF
18	Jun-84	Chloramine-T	topical soluble powder	salmonids	bacterial gill disease	Accentive	NC	Closed (transfer)
19	Dec-83	Oxytetracycline	premix	alligators	bacterial infection	Phibro	S	z-Inactive
20	Jul-84	Chloramine-T	topical soluble powder	catfish	bacterial infection	Accentive	S	z-No Proj
21	Dec-82	Albendazole	oral suspension	sheep	liver flukes	Pfizer	NC	z-No Proj
22	Aug-84	Penicillin	injectable	ducks	erysipelas	Pfizer	NC	z-No Proj
23	Apr-83	Lutalyse	injectable	goats	anestrus	Pharmacia	S	z-No Proj
24	Apr-83	Monensin	premix	goats	coccidiosis	Elanco	S	z-Dup
25	May-83	Xylazine	injectable	cattle	anesthetic	Bayer	S	z-No Proj
26	Jun-83	Mebendazole	oral paste	goats	GI parasites	Schering	S	z-No Proj
27	May-83	Spectinomycin	intramammary infusion	cattle	mastitis	Bimeda	S	z-No Proj
28	Oct-83	Chloramine-T	topical soluble powder	salmonids	external bacterial infections	Natchez	W	z-Dup
29	Oct-83	Lasalocid	premix	goats	coccidiosis	Alpharma	W	z-No Proj
30	Oct-83	Bacitracin	premix	quail	ulcerative enteritis	Alpharma	S	Approved
31	Nov-83	Praziquantel	premix/ oral capsule	wild ducks, geese, mute swan	schistosomiasis	Bayer	NC	z-Inactive
32	Dec-83	Ampicillin	oral bolus	goats	enteritis	Fort Dodge	W	z-No Proj
33	Dec-83	Amoxicillin trihydrate	injectable	dairy goats (nonlactating)	bacterial pneumonia	Pfizer	W	z-Dup
34	Dec-83	Amoxicillin trihydrate	oral bolus	dairy goats (nonlactating)	bacterial enteritis	Pfizer	W	z-No Proj
35	Dec-83	Amoxicillin trihydrate	oral bolus	dairy goats (nonlactating)	bacterial enteritis	Pfizer	W	z-No Proj
36	Dec-83	Ampicillin	injectable	dairy goats (lactating)	bacterial pneumonia	Fort Dodge	W	z-No Proj
37	Dec-83	Ampicillin	injectable	dairy goats (nonlactating)	bacterial pneumonia & enteritis	Fort Dodge	W	z-No Proj
38	Dec-83	Ampicillin	oral bolus	dairy goats (nonlactating)	enteritis	Fort Dodge	W	z-No Proj
39	Dec-83	Chlortetracycline	premix	dairy goats (nonlactating)	bacterial infections	Alpharma	W	z-No Proj
40	Dec-83	Chlortetracycline	premix	dairy goats	bacterial pneumonia	Alpharma	W	z-Dup
41	Dec-83	Neomycin sulfate	oral soluble powder	dairy goats (nonlactating)	enteritis	Pharmacia	W	z-No Proj
42	Dec-83	Oxytetracycline	injectable (100 mg/ml)	dairy goats (nonlactating)	bacterial infections	Pfizer	W	z-No Proj
43	Dec-83	Oxytetracycline	injectable	dairy goats (nonlactating)	bacterial pneumonia	Pfizer	W	z-Inactive
44	Dec-83	Oxytetracycline	injectable (long acting)	dairy goats (nonlactating)	bacterial infections	Pfizer	W	z-Dup
45	Dec-83	Oxytetracycline	injectable (50 mg/ml)	dairy goats (nonlactating)	bacterial infections	Pfizer	W	z-Dup
46	Dec-83	Benzathine penicillin	injectable	dairy goats	bacterial pneumonia	Fort Dodge	W	z-No Proj
47	Dec-83	Procaine Penicillin	injectable	dairy goats	bacterial infections	Fort Dodge	W	z-No Proj
48	Dec-83	Sulfachloropyridazine	oral powder	dairy goats	enteritis	Fort Dodge	W	z-No Proj
49	Dec-83	Sulfachloropyridazine	injectable	dairy goats	enteritis	Fort Dodge	W	z-No Proj
50	Dec-83	Sulfabromomethazine	oral bolus	dairy goats	bacterial infections	Merial	W	z-No Proj
51	Dec-83	Sulfachloropyridazine	oral bolus	dairy goats	enteritis	Fort Dodge	W	z-No Proj
52	Dec-83	Sulfadimethoxine	oral drinking water solution	dairy goats	bacterial pneumonia	Alpharma	W	z-No Proj
53	Dec-83	Sulfadimethoxine	oral bolus?	dairy goats	bacterial pneumonia	Alpharma	W	z-No Proj
54	Dec-83	Sulfadimethoxine	oral powder	dairy goats	bacterial pneumonia	Alpharma	W	z-No Proj
55	Dec-83	Sulfadimethoxine	oral powder	dairy goats	bacterial pneumonia	Alpharma	W	z-No Proj
56	Dec-83	Sulfaethoxypyridazine	injectable	dairy goats	bacterial infections	American Cyanamid	W	z-No Proj
57	Dec-83	Sulfaethoxy- pyridazine	oral drinking water solution	dairy goats	bacterial infections	American Cyanamid	W	z-No Proj
58	Dec-83	Sulfaethoxy- pyridazine	oral bolus	dairy goats	bacterial infections	American Cyanamid	W	z-No Proj
59	Dec-83	Sulfamethazine	oral sustained release tablets	goats	bacterial pneumonia	Bayer	W	z-No Proj
60	Dec-83	Oxytetracycline	injectable	goats	enteritis	Pharmacia	W	z-No Proj
61	Dec-83	Tylosin	injectable	goats	bacterial pneumonia	Elanco	W	z-No Proj
62	Jan-84	Benzathine cloxacillin	intramammary infusion	dairy goats	mastitis	Pfizer	W	z-No Proj
63	Jan-84	Benzathine cloxacillin (Dry-Clox)	intramammary infusion	dairy goats	mastitis	Pfizer	W	z-No Proj
64	Jan-84	Cephapirin benzathine	intramammary infusion	dairy goats	mastitis	Fort Dodge	W	z-No Proj
65	Jan-84	Novobiocin	intramammary infusion	dairy goats	mastitis	Pharmacia	W	z-No Proj

ADR	Date rec'd	Drug	Formulation	Species	Indication	Firm	Reg	Status
66	Jan-84	Novobiocin/ penicillin	intramammary infusion	dairy goats	mastitis	Pharmacia	W	z-Inactive
67	Jan-84	Hetacillin	intramammary infusion	goats	mastitis	Fort Dodge	W	z-No Proj
68	Jan-84	Sodium cepharin	intramammary infusion	goats	mastitis	Fort Dodge	W	z-No Proj
69	Jan-84	Sodium cloxacillin	intramammary infusion	goats	mastitis	Pfizer	W	z-No Proj
70	Jan-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease	——	NE	z-No Proj
71	Jan-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease	——	NE	z-No Proj
72	Feb-84	Diquat	immersion	brown trout	bacterial gill disease	Chevron	NE	z-No Proj
73	Feb-84	Furazolidone	premix	trout	furunculosis	Fort Dodge	NE	z-No Proj
74	Feb-84	Sulfamethazine	oral sustained release tablets	sheep	bacterial pneumonia	Bayer	NE	z-Inactive
75	Feb-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease	——	NE	z-Dup
76	Feb-84	Ethoxyquin	premix	sheep	bittersweet poisoning	Monsanto	S	z-No Proj
77	Mar-84	Clinoprost tromethamine??	injectable	sheep	breeding synchronization	Pharmacia	W	z-No Proj
78	Mar-84	Ivermectin		sheep	G.I. parasites	Merial	W	z-No Proj
79	Mar-84	Lasalocid	premix	sheep	coccidiosis	Alpharma	W	z-No Proj
80	Mar-84	Levamisole	Oral soluble powder	sheep	G.I. parasites	American Cyanamid	W	z-No Proj
81	Mar-84	Monensin	premix	sheep	coccidiosis	Elanco	W	z-No Proj
82	Mar-84	Norgesterone	injectable	sheep	estrus synchronization	Bimeda	W	z-No Proj
83	Mar-84	Oxytetracycline	injectable	sheep	bacterial pneumonia	Pfizer	W & NC	Closed
84	Mar-84	Spectinomycin	injectable/oral soluble powder	sheep	colibacillosis	Bimeda	W	z-No Proj
85	Mar-84	Tylosin	premix	sheep	Mycoplasma pneumonia	Elanco	W	z-No Proj
86	Mar-84	Progesterone	injectable	sheep	anestrus	——	NC	z-No Proj
87	Apr-84	Amoxicillin trihydrate	injectable	sheep	bacterial pneumonia	Pfizer	W	PMF
88	Apr-84	Ampicillin	injectable	sheep	bacterial pneumonia	Pfizer	W	z-No Proj
89	Apr-84	Virginiamycin	premix	rabbits	bacterial infections	Phibro	W	z-No Proj
90	May-84	Monensin	premix	quail	coccidiosis	Elanco	S	Approved
91	May-84	Erythromycin	premix	quail	chronic respiratory disease	Abbott Labs	S	z-No Proj
92	May-84	Ipronidazole	oral	quail	blackhead	Alpharma	S	z-No Proj
93	May-84	Isoxsuprine HCl	Oral tablets	horse	navicular disease	Bimeda	S	z-No Proj
94	May-84	Di-N-Butyl Tin Oxide	immersion	channel catfish	tapeworms	M & T	S	z-No Proj
95	May-84	Levamisole	Oral soluble powder	goats	G.I. parasites	Schering	NE	PMF
96	May-84	Sulfadimethoxine /ormetoprim	premix	catfish	bacterial infections	Alpharma	S	Approved
97	May-84	Tricaine methanesulfonate	topical solution	salmonids	anesthetic	Argent Labs	S	z-No Proj
98	Aug-84	Levamisole	Oral soluble powder	sheep	G.I. parasites	Schering	NE	z-No Proj
99	Aug-84	Sulfaquinoxaline	premix	pheasants	coccidiosis	Merial	S	z-No Proj
100	May-84	Mebendazole	oral soluble powder	goats	G.I. parasites	Schering	S	z-No Proj
101	May-84	Methylene blue	injectable	cattle	nitrate poisoning	Hanford	NE	z-No Proj
102	May-84	Erythromycin thiocyanate	premix	mink	enteritis	Bimeda	NC	z-No Proj
103	Aug-84	Griseofulvin	oral soluble powder	rabbits	ringworm	Schering	NE	z-No Proj
104	Aug-84	Monensin	premix	rabbits	coccidiosis	Elanco	NE	z-No Proj
105	Aug-84	Procaine penicillin	injectable	rabbits	pasteurellosis	Pfizer	NE	z-No Proj
106	Aug-84	Azaperone	injectable	wild ungulates	immobilization	Schering	NE	z-No Proj
107	Sep-84	Ivermectin	injectable	rabbits	ear mites	Merial	S	Active
108	Sep-84	Chlortetracycline	injectable	rabbits	pasteurellosis	American Cyanamid	S	z-No Proj
109	Sep-84	Sulfadimethoxine /ormetoprim	premix	rabbits	hepatic coccidiosis	Alpharma	S	z-No Proj
110	Sep-84	Ivermectin	Injectable	fox	ear mites	Merial	S	Approved
111	Sep-84	Decoquinate	premix	goats	coccidiosis	Alpharma	NE	Approved
112	Nov-84	Clorsulon	oral suspension	goats	liver flukes	Merial	S	PMF
113	Nov-84	Amprolium	oral soluble powder/ premix	quail	coccidiosis	Merial	NE	z-No Proj
114	Nov-84	Monensin	premix	quail	coccidiosis	Elanco	NE	z-Dup
115	Nov-84	Salinomycin	premix	quail	coccidiosis	Alpharma	NE	Approved
116	Dec-84	Phenylbutazone	oral bolus?	sheep	arthritis	Schering	NE	z-No Proj
117	Dec-84	Lasalocid	premix	goats	coccidiosis	Alpharma	S	z-Dup
118	Jan-85	Tiamulin	premix	trout	red mouth disease	Boehringer	NE	z-No Proj
119	Jan-85	Sodium fluoride	premix	salmonids	bacterial kidney disease	——	NE	z-No Proj
120	Feb-85	Oxolinic acid	premix	salmonids	furunculosis, vibriosis	Parke-Davis	W	z-Inactive
121	May-85	Amoxicillin	intramammary infusion	dairy goats	mastitis	Pfizer	W	z-No Proj
122	May-85	Lasalocid	premix	rabbits	coccidiosis	Alpharma	S	Approved
123	Oct-85	Botram 75 W	soluble powder	bees	foulbrood	——	W	z-No Proj
124	Jan-86	Fenbendazole	oral suspension	goats	GI parasites	Intervet	NC	Approved
125	Jul-85	Ivermectin	injectable	Am. bison	hypodermosis	Merial	NC	Approved
126	Oct-85	Clorsulon	oral suspension	sheep	liver flukes	Merial	NE	z-No Proj
127	Nov-85	Fenbendazole	premix	bighorn sheep	lungworms	Intervet	W	Approved
128	Dec-85	Amprolium	oral drinking water solution	swine (neonates)	coccidiosis	Merial	S	z-No Proj
129	Jan-86	Levamisole	Oral soluble powder	quail	endoparasites	Schering	S	z-No Proj
130	Jan-86	Chlorine dioxide	topical solution	salmonids	furunculosis, bacterial gill disease	——	NE	z-No Proj
131	Feb-86	Benzocaine	topical soluble powder	salmonids	anesthesia	——	NC	z-No Proj
132	Mar-86	Melatonin	premix	sheep	anestrus	——	NC	z-No Proj
133	Mar-86	Lactic acid	injectable	sheep (lambs)	chemical castration	Boehringer	NE	z-No Proj
134	Mar-86	Levamisole	oral soluble powder	goats	GI parasites	Schering	NE	z-Dup
135	Jul-86	Erythromycin	premix	salmonids	bacterial kidney disease	Bimeda	W	Active
136	Aug-86	Sulfadimethoxine /ormetoprim	premix	quail	coccidiosis	Alpharma	NE	z-No Proj
137	Aug-86	Sulfadimethoxine /ormetoprim	premix	chukar partridges	coccidiosis	Alpharma	NE	Approved
138	Oct-86	Virginiamycin	premix	alligators	hatchling alligator syndrome	Phibro	S	z-Inactive
139	Nov-86	Ivermectin	injectable	cattle	ticks	Merial	S	z-No Proj
140	Feb-87	Amprolium	oral soluble powder premix	rabbits	coccidiosis	Merial	W	z-No Proj
141	Feb-87	Ivermectin	injectable	rabbits	ear mites	Merial	NE	z-Dup
142	Feb-87	Oxytetracycline	premix	rabbits	bacterial infections	Phibro	W	z-No Proj
143	Jan-87	Lasalocid	premix	rabbits	coccidiosis	Alpharma	W	z-Dup

ADR	Date rec'd	Drug	Formulation	Species	Indication	Firm	Reg	Status
144	Sep-87	Morantel tartrate	premix	goats	GI parasites	Phibro	S	Approved
145	Sep-87	Enrofloxacin	premix	salmonids	furunculosis	Bayer	NE	z-Inactive
146	Sep-87	Enrofloxacin	premix	salmonids	bacterial kidney disease	Bayer	NE	z-Inactive
147	Oct-87	Ivermectin	injectable/oral suspension	mink	GI parasites	Merial	NC	z-No Proj
148	Oct-87	Amprolium	oral soluble powder/ premix	mink	coccidiosis	Merial	NC	z-No Proj
149	Oct-87	Sulfathiazole	oral soluble powder	mink	bacterial enteritis	Fort Dodge	NC	z-No Proj
150	Oct-87	Sulfadimethoxine	wsp/tablets/ oral suspension	mink	coccidiosis, resp. and UT infections	Schering	NC	z-No Proj
151	Oct-87	Ivermectin	injectable/oral suspension	foxes	GI parasites	Merial	NC	z-No Proj
152	Oct-87	Amprolium	soluble powder/ premix	foxes	coccidiosis	Merial	NC	z-No Proj
153	Oct-87	Sulfathiazole	soluble powder	foxes	bacterial enteritis	Fort Dodge	NC	z-No Proj
154	Oct-87	Sulfadimethoxine	oral soluble powder/tablets/oral suspension	foxes	coccidiosis, resp. and UT infections	Schering	NC	z-No Proj
155	Oct-87	Ivermectin	injectable	fish	external crustacean and internal nematode	Merial	W	z-No Proj
156	Oct-87	Praziquantel	premix/ injectable	fish	cestodes and trematodes	Bayer	W	z-No Proj
157	Nov-87	Ivermectin	injectable	ranch foxes	ear mites	Merial	NC	z-No Proj
158	Nov-87	Tricaine methanesulfonate	topical soluble powder	striped bass	anesthesia	Argent	S	z-No Proj
159	Nov-87	Sulfadimethoxine /ormetoprim	premix	striped bass	bacterial infections	Alpharma	S	z-No Proj
160	Nov-87	Formalin	topical solution	striped bass	external protozoan parasites	Argent	S	z-No Proj
161	Nov-87	Oxytetracycline	premix	striped bass	pasteurellosis	Phibro	S	z-Inactive
162	Mar-88	Fumagillin dicyclohexylamine	premix/ injectable	salmonids	proliferative kidney disease	Abbott	W	z-No Proj
163	Mar-88	Fenbendazole	premix	pheasants	gapeworm	Intervet	W	z-No Proj
164	Mar-88	Morantel tartrate	premix/oral bolus	sheep	GI parasites	Phibro	W	z-No Proj
165	Mar-88	Ceftiofur	injectable	sheep	bacterial pneumonia	Pfizer	W	Approved
166	Mar-88	Ceftiofur	injectable	goats	bacterial pneumonia	Pharmacia	W	z-Dup
167	Apr-88	Lincomycin/spectinomycin	oral soluble powder	quail	air sacculitis	Pharmacia	S	z-No Proj
168	Apr-88	Fenbendazole	oral soluble powder	quail	GI parasites	Intervet	S	z-No Proj
169	Jun-88	Formalin	oral soluble powder	penaeid shrimp	External protozoan parasites	Argent	W	Approved
170	Feb-89	Ceftiofur	injectable	sheep	bacterial pneumonia	Pharmacia	W	z-Dup
171	Feb-89	Ceftiofur	injectable	goats	bacterial pneumonia	Pfizer	W & NC	Approved
172	Feb-89	Zinc bacitracin	premix	rabbits	post-weaning enteritis	Schering	W	z-No Proj
173	Mar-89	Ethylenedinitrilo tetraacetic acid copper	injectable	sheep	copper deficiency	Veterinary Research & Development	W	z-No Proj
174	Mar-89	Erythromycin	premix/ injectable	salmonids	bacterial kidney disease	Bimeda	W	z-Inactive
175	Apr-89	Enrofloxacin	premix	American eels	Aeromonas salmonicida infections	Bayer	S	z-No Proj
176	May-89	Amoxicillin (keep w/ 33)	injectable	dairy goats (lactating)	bacterial pneumonia	Pfizer	W	z-Inactive
177	May-89	Enrofloxacin	oral drinking water solution	rabbits	pasteurellosis	Bayer	NE	z-Inactive
178	Sep-89	Spectinomycin	injectable/oral soluble powder	ducks	colibacillosis, salmonellosis	Pharmacia	NC	z-Inactive
179	Dec-89	PD 127391 (fluoroquinolone)	oral drinking water solution	cockatiels	psittacosis	Fort Dodge	NE	z-Inactive
180	Oct-89	Ceftiofur	intrauterine	dairy cattle	metritis	Pharmacia	W	z-No Proj
181	Nov-89	Morantel tartrate	premix/oral bolus	sheep	GI parasites	Phibro	S	z-No Proj
182	Nov-89	Albendazole	premix/block	white tailed deer	meningeal worm	Intervet	NC	z-No Proj
183	Nov-89	Metaclopramide	implant	cattle	fescue toxicosis	A.H. Robins	S	z-No Proj
184	Apr-90	PD 117,596 (fluoroquinolone)	premix	salmonids	furunculosis	Fort Dodge	NE	z-No Proj
185	May-90	Fenbendazole	premix/feed block	white tailed deer	meningeal worm	Intervet	NC	z-No Proj
186	May-90	Sodium carbonate peroxyhydrate	topical soluble powder	channel catfish	external protozoan parasites	——	S	z-No Proj
187	May-90	Avermectin (Moxidectin)	biobullet implant	bighorn sheep	scabies, GI parasites, lungworm	Wildlife Labs	W	z-No Proj
188	May-90	Avermectin (Moxidectin)	biobullet implant	deer	GI parasites, external parasites	Wildlife Labs	W	z-No Proj
189	Jun-90	Sulfathiazole	premix	mink	bacterial pneumonia (Pseudomonas)	Boehringer	NC	z-No Proj
190	Jul-90	Ceftiofur	biobullet implant	bighorn sheep	bacterial pneumonia	Pharmacia	W	z-No Proj
191	Aug-90	Lasalocid	premix	chukar partridges	coccidiosis	Alpharma	NE	Approved
192	Aug-90	Ethylene vinyl acetate	pellet bait binder	lobsters, crabs	bait binder	DuPont	NE	z-No Proj
193	Oct-90	Sarafloxacin	premix	alligators	hatchling alligator syndrome	Abbott	S	z-No Proj
194	Nov-90	Cephapirin	intramammary infusion	dairy goats	mastitis	Fort Dodge	S	z-Dup
195	Nov-90	Ivermectin	premix	bighorn sheep	scabies	Merial	W	z-No Proj
196	Feb-91	Ivermectin	pour-on	llamas	GI parasites	Merial	W	z-No Proj
197	Feb-91	Ivermectin	pour-on	red deer	GI parasites and lungworm	Merial	W	z-Inactive
198	Apr-91	Ceftiofur	injectable	rabbits	pasteurellosis	Pharmacia	W	z-Inactive
199	Mar-91	Enrofloxacin	soluble powder	penaeid shrimp	bacterial infections	Bayer	W	z-Inactive
200	Mar-91	Erythromycin	soluble powder/premix	penaeid shrimp	bacterial infections	Bimeda	W	z-No Proj
201	Mar-91	Trichlorfon	soluble powder	channel catfish	insect predation	Bayer	S	z-No Proj
202	Feb-91	Ivermectin/ Clorsulon	injectable	llamas	GI parasites, liver flukes	Merial	W	z-No Proj
203	Feb-91	Enrofloxacin	premix	striped bass	bacterial infections	Bayer	S	z-No Proj
204	Oct-91	Nitrofurazone	topical soluble powder	shrimp	bacterial infections	Argent Labs	S	z-No Proj
205	Oct-91	Copper	topical solution (concentrate)	shrimp	bacterial infections	Argent Labs	S	z-No Proj
206	Nov-91	Albendazole	premix/feed block	white tail deer	meningeal worm	Pfizer	NC	z-No Proj
207	Dec-91	Captan	topical soluble powder	sheep	club lamb fungus	Drexel Chemical	NC	z-No Proj
208	Dec-91	Trifluralin	topical solution (concentrate)	shrimp	mycosis	Elanco	W	z-No Proj
209	Jan-92	Amoxicillin	premix	salmonids	furunculosis	——	W	z-Inactive
210	Mar-92	Fenbendazole (216 active)	premix	red deer	G.I. parasites	Intervet	S	z-No Proj
211	Mar-92	Ivermectin	blocks	bighorn sheep	psoroptic mange	Merial	W	z-No Proj
212	Apr-92	Metaclopramide	oral bolus	cattle	fescue toxicosis	——	S	z-No Proj

ADR	Date rec'd	Drug	Formulation	Species	Indication	Firm	Reg	Status
213	Apr-92	Sarafloxacin	premix	striped bass	septicemia	Abbott	S	z-No Proj
214	Apr-92	Enrofloxacin	premix	hybrid striped bass	columnaris disease	Bayer	S	z-No Proj
215	Apr-92	Sarafloxacin	premix	channel catfish	enteric septicemia and motile Aeromonas septicemia	Abbott	S	z-Inactive
216	May-92	Fenbendazole	premix	fallow deer	GI parasites	Intervet	S	Active
217	May-92	Tylosin	soluble powder	honey bees	foul brood	Elanco	W	Approved
218	Sep-92	Phenothiazine	block/pellet/ liquid	sheep, goats	GI parasites	Schering	NE	z-No Proj
219	Sep-92	N,N'-bis-(dichloroacetyl)-1-8 octane diamine	premix	timber wolves	antispermatogenic contraceptive	Sterling	NC	z-No Proj
220	Nov-92	Oxytetracycline	premix	Chinook salmon	columnaris disease, vibriosis	Phibro	W	z-No Proj
221	Nov-92	Oxytetracycline	premix	white sea bass	columnaris disease, vibriosis	Phibro	W	z-No Proj
222	Nov-92	Ivermectin	pour-on	American bison	GI parasites	Merial	NC	Inactive/ waived
223	Dec-92	Ceftiofur	injectable	goats	bacterial pneumonia	Pharmacia	S	z-Dup
224	Dec-92	Procaine penicillin G	injectable	goats	bacterial pneumonia	Pfizer	S	z-No Proj
225	Dec-92	Erythromycin	injectable	goats	bacterial pneumonia	Bimeda	S	z-No Proj
226	Dec-92	Tylosin	injectable	goats	bacterial pneumonia	Elanco	S	z-No Proj
227	Dec-92	Sulfadimethoxine	injectable	goats	bacterial pneumonia	Alpharma	S	z-No Proj
228	Jan-93	Ceftiofur	injectable	veal calves	respiratory infections	Pharmacia	NC	z-Inactive
229	Jan-93	Zinc bacitracin	premix	veal calves	enteric disorders, feed efficiency	Alpharma	NC	z-No Proj
230	Jan-93	Ivermectin	sustained release oral bolus	reindeer	warbles	Merial	W	z-No Proj
231	Feb-93	Copper sulfate	topical soluble powder	channel catfish	external protozoa	——	S	Closed (transfer)
232	Mar-93	Human chorionic gonadotropin	injectable	striped bass, white bass, hybrid striped bass	spawning aid	Intervet	S	z-No Proj
233	Mar-93	Enrofloxacin	injectable	ducks	colibacillosis, salmonellosis, pasteurellosis (anatipestifer)	Bayer	NC	z-No Proj
234	Jun-93	Luteinizing hormone releasing hormone analog	injectable	various fish	spawning aid	——	W	z-No Proj
235	Jul-93	Lasalocid	premix	pheasant	coccidiosis	Alpharma	NC	Active
236	Jul-93	Clopidol	premix	pheasant	coccidiosis	Aventis	NC	Inactive/ waived
237	Aug-93	Ivermectin	water	gamebirds	GI parasites	Merial	NC	z-No Proj
238	Sep-93	Formalin	topical soluble powder	Finfish and eggs	External fungal & protozoan parasites	Argent	W	Approved
239	Sep-93	Carp Pituitary	injectable	White Sturgeon	spawning aid	Stoller	W	z-No Proj
240	Sep-93	Potassium permanganate	topical soluble powder	White Sturgeon	External fungal & protozoan parasites	Carus Chemical	W	z-No Proj
241	Sep-93	Oxytetracycline	premix	White Sturgeon	Internal bacterial	Phibro	W	z-No Proj
242	Sep-93	Oxytetracycline	immersion	White Sturgeon	External bacterial	Pfizer	W	z-No Proj
243	Sep-93	Sarafloxacin	premix	White Sturgeon	Internal bacterial	Abbott	W	z-No Proj
244	Sep-93	Oxytetracycline	premix	various fish	otolith marking columnaris	Phibro	NC	z-No Proj
245	Sep-93	Oxytetracycline	immersion	various fish	otolith marking	Pfizer	NC	Approved
246	Sep-93	Tilmicosin phosphate	injectable	sheep	chronic respiratory	Elanco	S	Approved
247	Oct-93	Diminazene aceturate	injectable	cattle	anaplasmosis piroplasmosis	Intervet	S	z-No Proj
248	Dec-93	Spectinomycin	injectable	veal calf	enteric colibacillosis	Fort Dodge	NC	z-No Proj
249	Aug-94	Oxytetracycline	injectable	veal calf	respiratory inf	Pfizer	NC	z-No Proj
250	Feb-94	Levamisole phosphate	injectable	bison	GI parasites Ostertagia	Schering	NC	z-No Proj
251	Aug-94	Ceftiofur	injectable	red deer	respiratory inf	Pharmacia	W	z-Inactive
252	Aug-94	Tilmicosin phosphate	injectable	veal calf	respiratory inf	Elanco	NC	TERMINATED
253	Aug-94	Fenbendazole	premix	bison	GI parasites	Intervet	S	z-No Proj
254	Aug-94	Clopidol	premix	rabbit	coccidiosis	Aventis	NC	z-No Proj
255	Jan-95	Salinomycin		rabbit	coccidiosis	Alpharma	NC	z-No Proj
256	Jan-95	Sulfadimethoxine & ormetoprim	premix	rabbit	coccidiosis	Intervet	NC	z-No Proj
257	Mar-95	Oxytetracycline	soluble powder	lobster	gaffkemia	Pfizer	NE	z-Inactive
258	Mar-95	Progesterone	CIDR	sheep	estrus synchronization	Pfizer	NC/W	Active
259	Apr-95	Hydrogen peroxide	topical	various fish	bacterial gill disease	Eko Nobel	NE	Closed
260	Apr-95	Hydrogen peroxide	topical	Atlantic salmon	sea lice	Eko Nobel	NE	z-Inactive
261	May-95	Ceftiofur	injectable	psittacine birds	gram-negative inf	Pharmacia	W	z-No Proj
262	Jun-95	Monensin	premix	rabbits	coccidiosis	Elanco	NC	z-No Proj
263	Oct-95	Erythromycin	premix	hybrid striped bass	strep infections	Bimeda	W	z-No Proj
264	Jan-96	Albendazole	premix	Emu	nem/trem/cest	Intervet	S	z-No Proj
265	Jan-96	Ceftiofur	injectable	Emu	bacterial infection	Pharmacia	S	z-No Proj
266	Jan-96	Ivermectin	injectable	Emu	nematodes, lice, mites	Merial	S	z-No Proj
267	Jan-96	Sarafloxacin	WSP	Emu	bacterial infection	Abbot	S	z-No Proj
268	Jan-96	Sulfadimethoxine	soluble powder	Emu	bacterial infection & coccidiosis	Pfizer	S	z-No Proj
269	Jan-96	Sarafloxacin	premix	catfish	Enteric septicemia	Abbott	W	z-Inactive
270	Mar-96	Amoxicillin	premix	hybrid striped bass	strep infections		W	z-Inactive
271	Apr-96	Carp Pituitary	injectable	various fish	spawning aid	Stoller fisheries	S	Active
272	Jul-96	Sulfadimethoxine & ormetoprim	premix	pheasants	bacterial infection & coccidiosis	Alpharma	NE	Active
273	Jul-96	Nitarsone	premix	partridge	blackhead	Alpharma	S	Inactive/ waived
274	Jul-96	Zoamix	premix	pheasants	growth, feed eff & coccidiosis	Alpharma	S	Inactive/ waived
275	Jul-96	Ceftiofur sodium	injectable	llamas, alpaca, fallow deer	respiratory infection	Pharmacia	W/S	z-No Proj
276	Jul-96	Fenbendazole	premix	Ostrich & Emu	nematodes	Intervet	S	z-No Proj

ADR	Date rec'd	Drug	Formulation	Species	Indication	Firm	Reg	Status
277	Jul-96	Potassium permanganate	topical	catfish	External ichthyophthirius multifilis	Carus Chemical	S	z-Inactive
278	Aug-96	Monensin sodium	premix	pheasants & partridges	coccidiosis	Elanco	S	z-No Proj
279	Aug-96	Lasalocid	premix	pheasants	coccidiosis	Alpharma	NC	z-Dup
280	Aug-96	Fenbendazole	premix	pheasants & partridges	gapeworm & capillaria	Intervet	S	Active
281	Aug-96	Deccox	premix	pheasants & partridges	coccidiosis	Alpharma	S	z-No Proj
282	Aug-96	Chlortetracycline	premix	pheasants & partridges	bacterial infections	Alpharma	NC	z-No Proj
283	May-97	Oxytetracycline HCl	soluble powder	walleye (larval fish)	columnaris	Pfizer	NE	z-No Proj
284	Jun-97	MGA/GnRH	feed/ injectable	sheep	estrus synchronization	Pharmacia/ Fort Dodge	W	z-Inactive
285	Nov-97	Oxytetracycline	feed	various fish	vibriosis	Phibro	NE	Active
286	Nov-97	Oxytetracycline	feed	tilapia	strep infections	Phibro	NE	z-Inactive
287	Feb-98	Ketamine	injectable	ostrich/emu	anesthetic	Fort Dodge	W	z-No Proj
288	Feb-98	Xylazine	injectable	ostrich/emu	sedative	Bayer	W	z-No Proj
289	Feb-98	Enrofloxacin	WSP	ostrich/emu	bacterial infections	Bayer	W	z-No Proj
290	Feb-98	Trimethoprim/ Sulfadiazine	oral	ostrich/emu	bacterial infections	Schering	W	z-No Proj
291	Jul-97	Ivermectin	oral bait	deer	GI parasites	Merial	S	z-Dup
292	Aug-97	Doxycycline	extruded feed	psittacines	Chlamydia	Kaytee	NC	z-No Proj
293	Mar-98	Imexon	Injectable	mink	Alleutian disease	Boehringer	W	z-No Proj
294	Sep-98	Lasalocid	premix	deer	coccidiosis	Alpharma	S	Active
295	Sep-98	Strontium Chloride	immersion	fish	otolith marking	Western Chemical	W	Active
296	Nov-98	Molybdate	injectable	sheep	copper toxicity	?	NC	z-No Proj
297	May-99	Triclabendazole	drench	deer/elk	liver flukes	Novartis	NC	z-No Proj
298	May-99	Lasalocid	oral	goats	coccidiosis	Alpharma	S	Active
299	Aug-99	Pirlimycin	intramammary	goats	mastitis	Pfizer	W	Pending
300	Aug-99	Moxidectin	topical	cage birds	mites face/airsac	Fort Dodge	S	z-No Proj
301	Feb-00	Decoquinate	in milk	calves	cryptosporidiosis	Alpharma	W	z-No Proj
302	Mar-00	Antimicrobials	immersion	shellfish	bacterial infection	?	W	z-No Proj
303	Apr-00	Banamine	injection	veal calves	anti inflammatory	Schering	NC	z-No Proj
304	Apr-00	Neomycin 325	soluble powder	veal calves	bacterial enteritis	Osborne	NC	z-No Proj
305	Apr-00	Chlortetracycline	soluble powder	veal calves	bacterial enteritis	Fort Dodge	NC	z-No Proj
306	Apr-00	Mu Se (selenium)	injection	veal calves	Se deficiency	Schering	NC	z-No Proj
307	Apr-00	Florfenicol	injection	veal calves	bacterial pneumonia	Schering	NC	z-Dup
308	Apr-00	Micotil	injection	veal calves	bacterial pneumonia	Elanco	NC	z-Dup
309	Apr-00	Sulfamethoxazole/trimethoprim 960	oral - tablets	veal calves	bacterial infections	?	NC	z-No Proj
310	Apr-00	Cephalexin	oral	veal calves	bacterial infections	?	NC	z-No Proj
311	May-00	Lincomycin	soluble powder	bees	American Foulbrood	Pfizer	W	Active
312	Jun-00	Imidocarb	injection	dairy cattle	anaplasmosis babesiosis	Schering	S	z-Inactive
313	Oct-00	Sulfadimethoxine & ormetoprim	premix	fish	bacterial infections	Alpharma	NE	Active
314	Oct-00	Tripelennamine HCl	injection	veal calves	Antihistamine	Fort Dodge	NC	z-No Proj
315	Oct-00	Amikacin	injection	veal calves	Diarrhea	Fort Dodge	NC	z-No Proj
316	Oct-00	Sulfachlor- pyridazine	injection or oral	veal calves	Diarrhea	Fort Dodge	NC	z-No Proj
317	Oct-00	Levamisole phosphate	injection	veal calves	GI parasites	Schering	NC	z-No Proj
318	Oct-00	Penicillin	injection	veal calves	bacterial infections	Fort Dodge	NC	z-No Proj
319	Oct-00	Chlortetracycline	oral	veal calves	respiratory infections	Alpharma	NC	z-No Proj
320	Oct-00	Tylosin	injection	veal calves	respiratory infections	Elanco	NC	z-No Proj
321	Oct-00	Apramycin	oral	veal calves	Diarrhea	Elanco	NC	z-No Proj
322	Oct-00	Sulfadimethoxine	injection or oral	veal calves	respiratory infections	Pfizer	NC	z-No Proj
323	Oct-00	Various products	various	veal calves	various	various	NC	z-Dup
324	Jan-01	Progesterone	CIDR	goats	estrus synchronization	Pfizer	W	Active
325	Jul-01	Florfenicol	injection	sheep	respiratory infections	Schering	W	Inactive/ waived
326	Jul-01	Florfenicol	injection	sheep	foot rot	Schering	W	z-Inactive
327	Jul-01	Florfenicol	injection	goats	respiratory infections	Schering	W	z-Inactive
328	Jul-01	Florfenicol	injection	goats	foot rot	Schering	W	z-Inactive
329	Oct-01	Florfenicol	injection	veal calves	respiratory infections	Schering	NC	TERMINATED
330	Oct-01	Apitol	patties	honey bees	Varroa mites	Wellmark	NC	z-No Proj
331	Mar-02	Arecoline (Cestolin)	oral tablets	gamebirds, pet birds, cocks	Tapeworms, ascarids, trichinosis	Wallance Pharmaceut.	S	z-No Proj
332	Oct-02	Oxytetracycline	Oral	abalone	withering syndrome	Phibro	W	Pending
333	Dec-02	Florfenicol	Oral	shrimp	necrotizing pancreatitis	Schering	NC	Active
334	Jun-03	Florfenicol	Oral	finfish	bacterial infection	Schering	NE	Active
335	Mar-05	Ovaprim (GnRHa & Domperidone)	Injectable	ornamental fish	spawning aid	Syndel	S	Pending
336	Mar-05	Metomidate	Injectable	ornamental fish	anesthetic	Syndel	S	Pending
337	Jan-06	Progesterone	CIDR	goats	estrus synchronization	Pfizer	W	z-Dup
338	Apr-06	Ceftiofur hydrochloride	Intramammary	goats	mastitis	Pfizer	W	Active
339	May-06	tulathromycin	Injection	sheep	respiratory infections	Pfizer	NC	Active
340	May-06	tulathromycin	Injection	goats	respiratory infections	Pfizer	NC	Active
341	Sep-06	Melatonin	Implant	sheep	reproductive aid	Ceva	NC	Pending