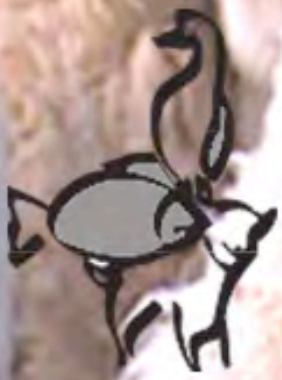
NRSP-7

National Research Support Project No. 7

The Minor Use Animal Drug Program

Annual Report 2008

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 33 Public Master File (PMF) publications in the *Federal Register*, an average of 1.4 per year during its 24 years of funding. In 2008, data from NRSP-7 was used in support of the FDA approval of Chloramine-T for control of bacterial gill disease in freshwater-reared salmonids. This formulation was approved to be used by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease. Tissue stability studies of progesterone implants for estrus synchronization in sheep are under review at FDA. Finally, during 2007 the regional coordinators published two 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 $440,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $335,000. 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 $40 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $4 to $10 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.

To date 342 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 18 active research projects involving nine animal species and 12 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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Appendix I
Animal Drug Requests Received by NRSP-7 through April 2008

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 $40 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $4 to $10 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

Stakeholders represent a major resource to the NRSP-7 program. It is through them that industry needs are determined and prioritized. Over the last five years, stakeholders have been invited to meet with the Technical Committee at FDA/CVM during the spring meeting. The table below identifies the stakeholder groups and their representative that have worked actively with NRSP-7

STAKEHOLDER REPRESENTATIVES

INDUSTRY	NAME	email
Dairy Goats (American Dairy Goat Association)	Linda Campbell	Linda@Khimaira.com
Deer (Texas Deer Association)	Scott Bugai	Docbatm90@aol.com
Deer (North American Deer Farmers Association)	Shane Donely Shawn Schafer	vetdonley@yahoo.com schafer@nadefa.org
Game Bird (North American Game Bird Association)	Eva Wallner-Pendleton	eaw10@psu.edu
Honey Bees (American Bee Keeping Association)	Troy Fore	troyfore@abfnet.org
Meat Goats (American Meat Goat Association)	Marvin Shurley	marvin@sonoratx.net
Rabbit (American Rabbit Breeders Association)	Chris Hayhow	ohiostatebuckeyes@kc.rr.com
Sheep (American Sheep Industry)	Paul Rodgers	prodgers2@earthlink.net

Gross annual farm gate income from production of minor animal species has been estimated at over $4.4 billion in the US. Economic impact to the US Gross Domestic Product is estimated at another $33.8 billion. 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. Before NRSP-7, private sponsors had supported approvals for the use of minor use drugs 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 4). 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.

US Farm Gate Value and Economic Impact of Minor Species by Industry and Leading States

Industry	Leading States	US Farm Gate Value [$M]	US Economic Impact [$M]
Game Bird	TX, NC, PA, KS, WI, NY, IL, SD, FL, MN, IA, GA, MS, IN & AL.	$830	$5,000
Rabbits	CA, GA, OH, PA, & TX	$20	$831
Honey Bees	ND, CA, SD, FL, MT, MN, TX, & WI.	$153	$16,000
Cervid	TX, PA, OH, FL, LA, IA, & KS	$894 (farming) $757 (hunting)	$3,000
Meat Goats	TX, TN, CA, GA, OK, NC, KY, MO, FL, & AL	$173.2 $189 (breeding)	$1,039
Dairy Goats	TX, OH, NY, PA, WI, WA, IN, CA, MD, MN, MI, FL, & KS.	$58.3 $14.8 (export)	$439
Sheep	TX, CA, WY & CO	$750	$4,500
Catfish/Aquaculture	**Catfish** MS, AK, AL, & LA **Trout** WA, WI, PA, ID, NC, OR, NY, CA, & CO	Catfish $480 Trout $87.5	$2,880 $159

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. Lisa Tell	California AES
Dr. Paul R. Bowser	New York AES
Dr. Alistair I. Webb	Florida AES
Dr. Ronald W. Griffith	Iowa AES

Funding

Unlike other years in which The Minor Use Animal Drug Program was funded through USDA Special Research Grant, administered by CSREES, in 2007 NRSP-7 received its funding through “off-the-top” Regional Research funds allocated to the Minor Use Program through the State Agriculture Experiment Stations. The program also 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 provided through the Program. Funding is provided for the National Drug Coordinator's part-time salary and the maintenance of an office. Total Federal funding for the Program has been $11 million averaging $424,000 per year. Overall, non-federal funding has averaged 40% of federal funding since 1991.

NRSP-7 Funding by Year and Source

	Source of Funding				
Year	Federal	State	Industrial	Other	% Nonfederal
1982	$240	nc	nc	nc	nc
1983	$240	nc	nc	nc	nc
1984	$240	nc	nc	nc	nc
1985	$240	nc	nc	nc	nc
1986	$229	nc	nc	nc	nc
1987	$229	nc	nc	nc	nc
1988	$229	nc	nc	nc	nc
1989	$229	nc	nc	nc	nc
1990	$226	nc	nc	nc	nc
1991	$450	$156	$29	$11	44%
1992	$464	$266	$11	$1.0	60%
1993	$464	$212	$0.3	$0.1	46%
1994	$611	$158	$0.0	$7.0	27%
1995	$550	$84	$0.0	$0.0	15%
1996	$550	$192	$0.0	$0.0	35%
1997	$550	$357	$0.0	$0.0	65%
1998	$550	$105	$97	$0.0	37%
1999	$550	$317	$10	$7.0	61%
2000	$550	$349	$10	$0.0	65%
2001	$549	$87	$39	$0.0	23%
2002	$588	$138	$30	$0.0	29%
2003	$588	$138	nc	nc	23%
2004	$491	$156	$23	nc	36%
2005	$588	$152	$2.4	nc	26%
2006	$588	$157	$0	nc	27%
2007	$279	$164	$0	nc	59%

nc = not computed

Objectives

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.

In 2008, data from NRSP-7 was used in support of the FDA approval of Chloramine-T for control of bacterial gill disease in freshwater-reared salmonids. This formulation was approved to be used by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease. Tissue stability studies of progesterone implants for estrus synchronization in sheep are under review at FDA. Finally, during 2007 the regional coordinators published two articles in peer-reviewed journals containing data developed in the Program.

To date 342 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

In 2008, data from NRSP-7 was used in support of the FDA approval of Chloramine-T for control of bacterial gill disease in freshwater-reared salmonids. This formulation was approved to be used by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease. Tissue stability studies of progesterone implants for estrus synchronization in sheep are under review at FDA. Finally, during 2007 the regional coordinators published two articles in peer-reviewed journals containing data developed in the Program.

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 33 Public Master File (PMF) publications in the *Federal Register*, an average of 1.4 per year during its 24 years of funding. (Table 2.1 The mean total expenditure per completed research for a drug approval or publication of a PMF was $440,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $335,000. 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 $40 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $4 to $10 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.

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PROGRAM ACTIVITY BY REGION
NORTHEAST REGION

INAD 9493 Hydrogen Peroxide as a Therapeutic Compound for Bacterial Gill Disease in Fish.
No additional work has been performed on this project during this study period.

SPECIES GROUPING PROJECT

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

A primary constraint in the availability of therapeutic compounds for the Aquaculture Community is the relatively large number of fish species that are currently cultured or that have significant potential as commercial species. Currently, research in support of a label for a therapeutic compound must be performed separately for each species for which the label is desired. We have undertaken a project designed to show the similarities in how drugs are handled by different fish species with the goal of supporting a species (crop) grouping concept for fish. We have conducted these studies in a collaborative effort with the Western Region NRSP7. Within this context, to date we have completed the following preliminary Human Food Safety/Tissue Depletion Studies using the following test articles as model compounds:

Oxytetracycline:

1. Walleyes, freshwater fish, 15C and 20C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass, saltwater fish, 20C and 25C
4. Summer Flounder, saltwater fish, 17C and 20C
5. Rainbow Trout, cold water trial (8C)

Romet-30:

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

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

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

Florfenicol (Effect of fish size)

1. Tilapia – 100 gm, freshwater fish,
   25C, 15 mg/Kg, 10d
2. Tilapia – 250 gm, freshwater fish,
   25C, 15 mg/Kg, 10d
3. Tilapia – 500 gm, freshwater fish,
   25C, 15 mg/Kg, 10d

Several attempts were made to conduct human food safety studies or Romet-30 in hybrid striped bass. The Sponsor has developed a product (Romet-TC) that circumvents the palatability problem and we anticipate efforts to complete the Human Food Safety/Tissue Elimination studies in that species soon.

WORK PLANNED FOR NEXT YEAR

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

No additional work is planned for this project in the upcoming year.

Species Grouping Project:

INAD 10-320 Oxytetracycline in Fish
INAD 10-823 Romet-30 in Fish

INAD 11-145 Aquaflor (Florfenicol) in Fish

We anticipate conducting Efficacy Studies in a collaborative effort with the New York State Department of Environmental Conservation. The particular focus of the efficacy trials will be for the treatment of bacterial diseases not currently on the label for salmonids and for the treatment of bacterial diseases of cool water species such as walleyes, muskellunge and tiger muskellunge (hybrid muskellunge X northern pike). These studies will be initiated when diagnosed field cases can be identified that will lend themselves to the implementation of controlled field studies. We also anticipate the completion of Human Food Safety trials with Romet-TC in Hybrid Striped Bass at 20C and 25C.

NORTH CENTRAL REGION

DR. RONALD W. GRIFFITH

ADR 258: Sheep CIDR-G Tissue Residue Stability

This study was performed by Dr. Dennis Hallford at New Mexico State University in cooperation with both the Western and North Central Regions. The assays for the freezer stability of progesterone have been completed, the data has been submitted to the CVM for review and arguments were submitted to CVM concerning the lack of residue in fresh liver. We are currently awaiting final word on whether the report will be accepted or whether we need to re-do all or part of the study.

ADR 324: Goat CIDR-G Tissue and Milk Residue

These studies are being supported by both the NC and Western Regions of NRSP-7. The in-life phase of milk residue study was performed at UC-Davis in fall 2007 and the analytical phase was performed by Dr. Hallford at New Mexico State University. The data from the study was recently submitted for QA to the Western Region. An issue arose that triplicate analyses needed to be performed on each milk sample if this were to be considered a depletion study. Dr. Hallford has re-configured the data and the statistical analysis to compare peak P4 levels (which is really the only critical criterion) and we will hopefully be OK with this data. The data indicate that progesterone levels in the milk of pregnant does are greater than progesterone levels in the milk of CIDR-treated does. Dr. Hallford plans on performing the tissue residue portion of the study this fall but wanted to wait for resolution of the sheep tissue residue issues. I have encouraged him to submit the goat protocol so that we can get it reviewed in time to begin the study.

ADR 324: Goat CIDR-G Effectiveness

The protocol was submitted and reviewed by ONADE. It was deemed not acceptable and there are numerous problems that need to be resolved dealing with the minimum number of study animals, location(s) of study, and whether we need to do dairy- and meat-breed goats as separate studies. ONADE is also requesting data be collected on reproductive safety

ADR 340: Draxxin Target Animal Safety in Goats

The in-life phases of the study were completed on March 22, 2008. The tissues from the untreated control and high-dose-group goats have been sectioned and stained. As soon as those are evaluated, we unmask the study and analyze the data. All the goats remained in good health except for one untreated control goat that developed respiratory disease. A few of the goats had some scattered lesions that seemed to be related to infectious processes rather

than any toxic effects of the drug. In addition to the TAS portion of the study, we collected tissues and plasma for tulathromycin analysis for publication purposes.

ADR 340: Draxxin Efficacy in Goats

The protocol for a natural exposure model has been accepted by CVM. However, the studies were predicted to take at least three years to complete and require a significant portion of the financial resources of the NC Region. An alternative protocol based upon determination of AUC/MIC was prepared and submitted. However, ONADE wanted us to base statistical significance by comparison to cattle AUC/MIC. We were asked to provide an alternative target for determining effectiveness. It was decided that we needed some preliminary analytical and MIC data in order to set a realistic target. We are currently collecting bacterial isolates to perform the MIC. We completed the in-life phase of a PK study on April 11, 2008 to give us an idea of where the AUC is going to fall. Those plasma samples were shipped to Scott Wetzlich in Lisa Tell's lab. Once we have the preliminary data, we will discuss our target AUC/MIC with ONADE.

ADR 340: Draxxin Tissue Residue

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

ADR 235: Lasalocid Efficacy in Pheasants

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

ADR 235: Lasalocid TAS in Pheasants

The protocol for this study was submitted to ONADE for review and hopefully will be returned by early June. Drs. McDougald and Fuller have agreed to perform this study as well. The North Central Region will be funding the study and has also funded a Veterinary Summer Scholar to work on this project in Dr. McDougald's lab.

ADR 235: Lasalocid Human Food Safety in Pheasants

The protocol for this study is nearing completion and will be submitted soon. Our target for this study is sometime in the fall of 2008. The Southern Region lab will be doing the tissue analyses.

ADR 341: Regulin (melatonin) implants for sheep

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

ADR 297: Fasinex (Triclabendazole) for Deer and Elk

No Activity to report.

Bioclip for Sheep

No activity to report.

SOUTHERN REGION

CURRENT PROJECTS

ACTIVE REGIONAL PROJECTS:

ADR 107 INAD 9557 Ivermectin & Rabbits

TAS study is complete and waiting for statistical analyses to be re-done and the report completed. The human safety *in vivo* has been completed and the assay should be finished within six weeks. Spiked samples were created and frozen contemporaneously so freezer stability work should be very quickly completed. The QC progress on ADR 280 will determine the speed and method with which these reports will proceed. Expected projections would be for a Winter submission.

ADR 271 INAD 9757 Crude Carp Pituitary

The author of the TAS study has moved and contact has been temporarily lost. Readings on the report are very bleak. Progress on contacting the investigator will be made to the monthly teleconference when appropriate.

ADR 280 INAD 10-063 Fenbendazole & Gamebirds

All in vivo work has been completed and a digital submission of the human safety study report was created. Unfortunately the QC unit was not happy with it and FDA indicated that it was not ready to review such submissions. It has been recast as a paper submission under the guidance of the Western Regions QA unit and is being sent back for further QC input. The TAS report is waiting for the other review before being also recast as a paper submission. Unless the QC fails, both of these will be submitted by Fall.

ADR 294 INAD 10-746 Lasalocid & Deer

Progress on both the deer and goat lasalocid projects depends on the human safety results as the sponsor has made it clear that, without a zero withdrawal time, they are not interested in amending their label. The problems have been a miscommunication with the probable investigator [TAMU] and HPLC problems. Both are being resolved. The HPLC problem occurred with major (and expensive) mechanical problems while the service contract had been allowed to lapse due to the funding crisis. The contract was re-instated but a time had to pass before repairs could be called for to avoid a pre-existing exclusion occurring. Progress on protocol and the assay validation will be reported to the teleconference as appropriate.

ADR 298 INAD 10-872 Lasalocid & Goats

See ADR # 294

ADR 210 Fenbendazole & Red Deer

We are waiting for results of the dose confirmation study being conducted by subcontract by the sponsor. That and possible collaboration with the TAMU group will probably determine the probability that the sponsor will continue with the project.

ADR 216 Fenbendazole & Fallow Deer

See ADR # 210

SPECIFIC PROJECTS PROPOSED FOR 2008

See ADRs 107 & 280 above for details of report submissions.

The development of the lasalocid projects will continued in the case of the assay validation [expected to be completed late summer] and the communication error [Southern

Region's solely] has been addressed and we are working to develop an active collaboration on this drug and possibly the fenbendazole & deer project.

The reported activities will require that we maintain lab and staff at GLP level although loss of some personnel with the funding cuts experience at the PI's laboratory has made that difficult.

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.

As usual we will be prepared to continued collaborative work with the other regions as requested. It is always possible that this may include unplanned studies to address critical needs and opportunities to collect data.

Finally we continue the development of the NRSP-7 web site with possible re-implementation of the RUSTi database.

OTHER ACTIVITIES

The NRSP-7 web site is maintained by the Southern Region. It attracts a daily average hit rate of 5-10 per day and has an international user base. We are working to introduce some interactive display of presentations and publications made to and by The Program.

WESTERN REGION

ACTIVE REGIONAL PROJECTS:

ADR 325: Florfenicol for sheep for respiratory disease

Western region is waiting for an update regarding the manufacturer status of this product.

ADR 324: Progesterone CIDRs for Goats

Target Animal Safety report has been accepted by FDA/CVM (February 20, 2008). Milk residue study has been completed and the data sent to UC Davis. CVM has provided comments regarding efficacy protocol. Protocol revision is underway.

ADR 272: **Romet for Gamebirds**

See species grouping report.

ADR 299: Pirlimycin for Dairy Goats

Project on hold until funding is identified and CIDR goat studies are completed.

ADR 295: Strontium Chloride for Salmonids. Steve Schroeder

There is nothing to report. Status of the project needs to be changed.

ADR 338: Spectramast™ LC Sterile Suspension for Mastitis in Dairy Goats

Project on hold until funding is identified and CIDR goat studies are completed.

ADR 135: Erythromycin in Salmonids

Mark Gaikowski with the U.S. Geological Survey - Upper Midwest Environmental Sciences Center in La Crosse, Wisconsin is working in conjunction with NRSP-7 to revise and review specific sections of the Environmental Assessment Report for resubmission to CVM. In order to address the CVM comments, a pilot chronic toxicity study with *Daphnia magna*, is currently underway, using erythromycin thiocyanate and diphenhydramine and the main study will be conducted later in the summer. The ultimate goal of these studies is to produce data that

will address CVM's concerns regarding chronic toxicity to aquatic insects. Other studies underway include a study to identify physico-chemical properties of erythromycin and a study to determine the microbial toxicity of various erythromycin transformation products. Once again, these results will be used to address the concerns expressed by CVM. The last study to be considered is characterization of leaching of erythromycin from feed, feces, and sediment.

ADR 311: Lincomycin soluble powder for foulbrood disease in Honeybees

Western region is waiting for the data summary from investigators for CVM submission. Dr. Margaret Oeller is assisting to facilitate this CVM submission.

COLLABORATIVE PROJECTS:

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

See Southern Region Report.

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

Species Grouping Fish:

See North Eastern Region Report.

Samples analysis for florfenicol is complete. For the fish species-grouping project, we have analyzed 120 muscle samples this year from trial number 2004-1.

ADR 324: Progesterone CIDRs for Goats: Milk Residue Study

Raw data for goat milk progesterone concentrations have been sent to UC Davis by Dr. Dennis Hallford from New Mexico State University.

ADR 340: Tulathromycin in Goats

QA was performed for the Target Animal Safety study in February and March by Ms. Ogletree.

QA review of TAS protocol is to be done by Ms. Sandra Ogletree.

The LCMS installation was completed in January 2008. The Western region has started working on establishing the approved analytical method in our laboratory.

OTHER PROJECTS:

Avian Species Grouping:

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

Excede (Ceftiofur Crystalline Free Acid) in Goats:

In collaboration with Drs. Rowe and Angelos, Dr. Elizabeth Dore (UC Davis 3rd year Food Animal Resident) completed the study evaluating use of Excede in non-lactating goats. The data from this study was compiled and presented at two scientific venues. The remainder of the study will be completed in June of 2008 in the lactating goats.

NRSP-7 PUBLICATIONS IN 2007

Topic-Popovic, N. J.G. Babish and P.R. Bowser. 2007. Observational study of hepatic cytochrome P-450 protein expression and activity in summer flounder (*Paralichtys dentatus*) following combination ormetoprim-sulfadimetoxine treatment. Chemotherapy 53:313-315.

Kosoff, R.E., C.-Y. Chen, G.A. Wooster, R.G. Getchell, A. Clifford, A.L. Craigmill and P.R. Bowser. 2007. Sulfadimethoxine and Ormetoprim residues in three species of fish after 5-day oral dosing in feed. Journal of Aquatic Animal Health 19:109-115.

SUBMITTED:

John G. Babish, Ph.D.
National Coordinator
Chair, Technical Committee

9/22/08
Date

L. Garry Adams, DVM, Ph.D.
Chair, Administrative Advisors

22 IX 08
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 2.1. Public Master Files (PMF) Published and New Animal Drug Approvals (NADA) by Drug

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	NADA
Bacitracin	Premix	Quail	Ulcerative enteritis	Avian	NADA
Ceftiofur	Injectable	Goats	Bacterial pneumonia	Ruminant	NADA
Ceftiofur	Injectable	Sheep	Bacterial pneumonia	Ruminant	NADA
Chlorimine T	Soluble powder	Salmonids	Bacterial gill disease	Aquatic	PMF
Clorsulon†	Oral suspension	Goats	Liver flukes	Ruminant	PMF
Decoquinate	Premix	Goats	Coccidiosis	Ruminant	NADA
Decoquinate	Premix	Sheep	Coccidiosis	Ruminant	NADA
Fenbendazole	Premix	Bighorn Sheep	Lungworms	Ruminant	NADA
Fenbendazole	Oral suspension	Goats	GI parasites	Ruminant	NADA
Formalin	Immersion	Finfish & eggs	External fungal & protozoan parasites	Aquatic	NADA
Formalin	Immersion	Penaeid shrimp	External protozoan parasites	Aquatic	NADA
Hydrogen peroxide	Immersion	Salmonids	Bacterial gill disease	Aquatic	NADA
Ivermectin	Injectable	American bison	Hypodermosis	Ruminant	NADA
Ivermectin	Injectable	Fox	Ear mites	Other	NADA
Ivermectin†	Injectable	Goats	GI parasites	Ruminant	PMF
Ivermectin	Injectable	Reindeer	Warbles	Ruminant	NADA
Lasslocid	Premix	Chukar partridges	Coccidiosis	Avian	NADA
Lasslocid	Premix	Rabbits	Coccidiosis	Other	NADA
Levamisole†	Soluble powder	Goats	GI parasites	Ruminant	PMF
Monesin	Premix	Goats	Coccidiosis	Ruminant	NADA
Monesin	Premix	Quail	Coccidiosis	Avian	NADA
Morantel tartrate	Premix	Goats	GI parasites	Ruminant	NADA
Oxytetracycline	Premix	Lobster	Gaffkemia	Aquatic	NADA
Oxytetracycline	Immersion	Finfish	Otolith marking	Aquatic	NADA
Salinomycin	Premix	Quail	Coccidiosis	Avian	NADA
Sulfadimethoxine/ ormetoprim	Premix	Catfish	Bacterial infections	Aquatic	NADA
Sulfadimethoxine/ ormetoprim	Premix	Chukar partridges	Coccidiosis	Avian	NADA
Thiabendazole	Premix	Pheasants	Gapeworm	Avian	NADA
Tilmicosin phosphate	Injectable	Sheep	Respiratory infections	Ruminant	NADA
Tylosin	Soluble powder	Honey bees	Foul brood	Other	NADA

†Public Master File; NADA = New Animal Drug Approval

Table 2.2. Public Master Files (PMF) Published and New Animal Drug Approvals (NADA) by Species

SPECIES	DRUG	FORMULATION	INDICATION	GROUP	STATUS
American bison	Ivermectin	Injectable	Hypodermosis	Ruminant	NADA
Bighorn Sheep	Fenbendazole	Premix	Lungworms	Ruminant	NADA
Catfish	Sulfadimethoxine/ ormetoprim	Premix	Bacterial infections	Aquatic	NADA
Chukar partridges	Lasslocid	Premix	Coccidiosis	Avian	NADA
Chukar partridges	Sulfadimethoxine/ ormetoprim	Premix	Coccidiosis	Avian	NADA
Finfish	Oxytetracycline	Immersion	Otolith marking	Aquatic	NADA
Finfish & eggs	Formalin	Immersion	External fungal & protozoan parasites	Aquatic	NADA
Fox	Ivermectin	Injectable	Ear mites	Other	NADA
Goats	Albendazole†	Oral suspension	Liver flukes	Ruminant	PMF
Goats	Ceftiofur	Injectable	Bacterial pneumonia	Ruminant	NADA
Goats	Clorsulon†	Oral suspension	Liver flukes	Ruminant	PMF
Goats	Decoquinate	Premix	Coccidiosis	Ruminant	NADA
Goats	Fenbendazole	Oral suspension	GI parasites	Ruminant	NADA
Goats	Ivermectin†	Injectable	GI parasites	Ruminant	PMF
Goats	Levamisole†	Soluble powder	GI parasites	Ruminant	PMF
Goats	Monesin	Premix	Coccidiosis	Ruminant	NADA
Goats	Morantel tartrate	Premix	GI parasites	Ruminant	NADA
Honey bees	Tylosin	Soluble powder	Foul brood	Other	NADA
Lobster	Oxytetracycline	Premix	Gaffkemia	Aquatic	NADA
Penaeid shrimp	Formalin	Immersion	External protozoan parasites	Aquatic	NADA
Pheasants	Amprolium	Premix	Coccidiosis	Avian	NADA
Pheasants	Thiabendazole	Premix	Gapeworm	Avian	NADA
Quail	Bacitracin	Premix	Ulcerative enteritis	Avian	NADA
Quail	Monesin	Premix	Coccidiosis	Avian	NADA
Quail	Salinomycin	Premix	Coccidiosis	Avian	NADA
Rabbits	Lasslocid	Premix	Coccidiosis	Other	NADA
Reindeer	Ivermectin	Injectable	Warbles	Ruminant	NADA
Salmonids	Chloramine T	Immersion	Bacterial gill disease	Aquatic	PMF
Salmonids	Hydrogen peroxide	Immersion	Bacterial gill disease	Aquatic	NADA
Sheep	Amoxicillin trihydrate†	Injectable	Bacterial pneumonia	Ruminant	PMF
Sheep	Ceftiofur	Injectable	Bacterial pneumonia	Ruminant	NADA
Sheep	Decoquinate	Premix	Coccidiosis	Ruminant	NADA
Sheep	Tilmicosin phosphate	Injectable	Respiratory infections	Ruminant	NADA

†Public Master File; NADA = New Animal Drug Approval

Table 3. NRSP-7 Active Projects

DRUG	FORMULATION	SPECIES	INDICATION	INAD
Carp Pituitary	Injectable	Fish (Various)	Spawning aid	9757
Erythromycin	Premix	Fish (Salmonids)	Bacterial kidney disease	6013
Fenbendazole	Premix	Deer	GI parasites	10-993
Fenbendazole	Premix	Pheasants & partridges	Gapeworm & capillaria	10-062
Florfenicol	Oral	Fish (finfish)	Bacterial infection	11-145
Florfenicol	Injection	Sheep	Respiratory infections	10-958
Ivermectin	Injectable	Rabbits	Ear mits	9557
Lasalocid	Premix	Deer	Coccidiosis	10-746
Lasalocid	Premix	Goats	Coccidiosis	10-872
Lasalocid	Premix	Pheasants	Coccidiosis	9096
Lincomycin	Soluble powder	Bees	American Foulbrood	10-776
Oxytetracycline	Feed	Fish (Various)	Vibriosis	10-320
Progesterone	CIDR	Goats	Estrus synchronization	11-389
Progesterone	CIDR	Sheep	Estrus synchronization	10-321
Strontium chloride	Immersion	Fish	Otolith marking	10-536
Sulfadimethoxine & ormetoprim	Premix	Fish	Bacterial infections	10-823
Tulathromycin	Injection	Goats	Respiratory infection	11-512
Tulathromycin	Injection	Sheep	Respiratory infection	11-513

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 2008

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
342	Oct-06	Moxidectin	Oral	goats	Internal parasites	Fort Dodge		Pending