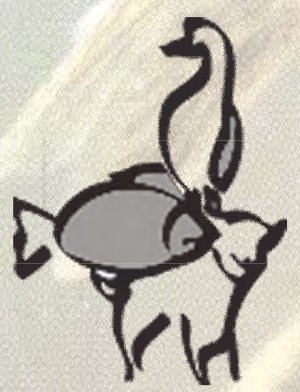
NRSP-7

National Research Support Project No. 7

The Minor Use Animal Drug Program

Annual Report
2007



http://www.nrsp7.org

Agricultural Researchers
Pharmaceutical Manufacturers
Animal Producers
USDA
FDA/CVM
Consumers

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 32 Public Master File (PMF) publications in the *Federal Register*, an average of 1.4 per year during its 23 years of funding. In 2007, data from NRSP-7 was used in support of the FDA approval of hydrogen peroxide as 35% PEROX-AID® (New Animal Drug Application 141-255). This formulation was approved as an external microbicide for the control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare (Flexibacter columnaris)*. Tissue stability studies of progesterone implants for estrus synchronization in sheep have been completed. Finally, during 2006 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 $454,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $346,000. 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 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 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 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.

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; in 2005 there were $151,962 in state appropriations with $2,360 in industry contributions; and $157,000 state appropriations in 2006. Overall, non-federal funding has averaged 40% 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 32 Public Master File (PMF) publications in the *Federal Register*, an average of 1.4 per year during its 23 years of funding (Table 2.1). The mean total expenditure per completed research for a drug approval or publication of a PMF was $454,000. Average federal expenditures per completed research for a drug approval or publication of a Public Master File was $346,000. 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 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 2007, data from NRSP-7 was used in support of the FDA approval of hydrogen peroxide as 35% PEROX-AID® (New Animal Drug Application 141-255). This formulation was approved as an external microbicide for the control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare (Flexibacter columnaris)*. Tissue stability studies of progesterone implants for estrus synchronization in sheep have been completed. Finally, the regional coordinators published 5 articles in peer-reviewed journals containing data developed in the Program.

PROGRAM ACTIVITY BY REGION

NORTHEAST REGION

WORK COMPLETED

Hydrogen Peroxide Project:

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

No additional work has been performed on this project during this study period.

Species Grouping Project:

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

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

have completed the following preliminary Human Food Safety/Tissue Depletion Studies using the following test articles as model compounds:

Oxytetracycline:

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

Romet-30:

1. Walleyes, freshwater fish, 20C and 25C
2. Tilapia, freshwater fish, 25C and 30C
3. Hybrid Striped Bass (would not accept the ration; see below)
4. Summer Flounder, saltwater fish, 17C and 20C

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

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

Florfenicol (Effect of fish size)

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

Several attempts were made to conduct human food safety studies or Romet-30 in hybrid striped bass. Although extremely active feeding on a non-medicated ration was observed during acclimation, the hybrid striped bass refused to consume the Romet-medicated ration on all attempts to initiate a trial. As a result, hybrid striped bass were eliminated from our testing matrix for Romet-30. The Sponsor has reported that they have developed a product that circumvents the palatability problem and we anticipate efforts to complete the Human Food Safety/Tissue Elimination studies in that species.

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

WORK PLANNED FOR THE COMING YEAR

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

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

Species Grouping Project:

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

We anticipate conducting Efficacy Studies, with a focus on oxytetracycline during the coming year. These studies will be performed in a collaborative effort with the New York State Department of Environmental Conservation. The particular focus of the efficacy trials will be for the treatment of bacterial diseases not currently on the label for salmonids and for the treatment of bacterial diseases of cool water species such as walleyes, muskellunge and tiger muskellunge (hybrid muskellunge X northern pike). These studies will be initiated when diagnosed field cases can be identified that will lend themselves to the implementation of controlled field studies.
During the coming year we anticipate the completion of the remaining tissue assays for samples generated from Human Food Safety/Tissue Elimination Studies of Aquaflor (Florfenicol) in Hybrid Striped Bass and Tilapia.

Rofenaid in Pheasants INAD 10-804

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

Minor Species Efforts in Goats

Preliminary efforts are underway to establish a minor species project in the Northeast Region that will focus on needs of the goat industry. This effort will be under the leadership of Dr. Mary Smith, Department of Clinical Sciences, College of Veterinary Medicine, Cornell University. Specific details of this study are still in the developmental stages.

NORTH CENTRAL REGION

CURRENT PROJECTS

Sheep CIDR-g Tissue Residue Stability

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

Goat CIDR-g Tissue and Milk Residue

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

Draxxin Efficacy in Goats

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

The second protocol submitted is a lung pharmacokinetic model. This study proposes to recover pulmonary fluids from treated goats over a period of time and then assay these fluids for tulathromycin levels. This would be coupled with antimicrobial susceptibility testing of 50 to 100 isolates of *Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* species from diverse geographic locations within the U.S. The lung fluid samples will be obtained at Iowa State University and analysed by LCMS at U.C., Davis. The antimicrobial susceptibility testing will be done at Texas A&M by Dr. Mitzy Libal.

Draxxin Target Animal Safety

The protocol has been submitted to CVM for review.

Draxxin Tissue Residue

The protocol has been submitted to CVM for review.

Lasalocid Efficacy in Pheasants

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

Bioclip in Sheep

No response from Merial to our inquiries.

Regulin (melatonin) implants for sheep

No activity to report. CEVA representative will be moving to Kansas City this spring. Contact will be made at that time to determine if CEVA is interested in supporting approval.

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

SOUTHERN REGION

CURRENT PROJECTS

RABBITS

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

FISH

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

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

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

BIRDS

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

DEER

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

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

WORK PLANNED FOR THE COMING PERIOD

- Maintain lab and staff at GLP level
- Submit early in the new year the all ivermectin for rabbit reports and all fenbendazole reports.
- Organize studies for gaining approval of fenbendazole & lasalocid in deer, and lasalocid in goats.
- Prepare, in coordination with the National Coordinator, INAD submissions for studies conducted under the aegis of the Southern Region. Initial preparation of written responses to CVM review of all of the data submitted for each project. This is often a time consuming and unrecognized activity associated with the completion of each project and may require considerable correspondence and conversation.
- Continued collaborative work with the other regions is anticipated and may include unplanned studies to address critical needs and opportunities to collect data.
- Continue the development of the NRSP-7 web site with full activation of the RUSTi database.
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WEB SITE MAINTENANCE

The NRSP-7.org web has continued to function well but is need of some development such as PowerPoint Presentations. The University is cranking-up security and is centralizing control of IT. We are concerned but we have been model citizens plus we actually got our original permission to host the web site without obvious use of

the ufl.edu domain from the current head of IT. The MUMSRx web database continues to be updated – it alone receives 1-2 hits each day. Rusti is now fully functional and Laura has returned to full-time work. We will be working with each coordinator to get active projects fully entered into the system.

NEW / PROPOSED PROJECTS:

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

WESTERN REGION

PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

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

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

ADR #135 – Erythromycin in Salmonids - FDA/CVM has contacted the Study Director, Dr. Christine Moffitt, stating that the Technical Section has been accepted as soon as there is an authorization letter from Abbott for CVM to use their proprietary toxicology data as the basis for the ADI. Once that is established, the Technical Section Complete letters for effectiveness, target animal safety, and human food safety will be complete. Dr. Moffitt is also reviewing the draft Environmental Assessment Report.

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

COLLABORATIVE PROJECTS:

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

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

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

NEW PROJECTS:

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

WORK PLANNED FOR 2007

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

NRSP-7 PUBLICATIONS IN 2006

Chen, C.-Y., C.-B. Chao and P.R. Bowser. 2006. Infection of tilapia *Oreochromis* sp. by *Vibrio vulnificus* in freshwater and low salinity environments. Journal of the World Aquaculture Society. 37(1):82-88.

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

Chen, C.-Y., C.-B. Chao and P.R. Bowser. 2007. Comparative histopathology of *Streptococcus*
iniae and *Streptococcus agalactiae*-infected tilapia. Bulletin of the European Association of Fish
Pathologists 27(1):2-9.

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 (in press).

Topic-Popovic, N. J.G. Babish and P.R. Bowser. 2006. Observational study of hepatic cytochrome P-450 protein expression and activity in summer flounder (*Paralichtys dentatus*) following combination ormetoprim-sulfadimetoxine treatment. Chemotherapy (in press)

SUBMITTED:

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

8/24/07
Date

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

27 VIII 07
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
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	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
Lincomycin	Soluble powder	Bees	American Foulbrood	10-776
Fenbendazole	Premix	Deer	GI parasites	10-993
Lasalocid	Premix	Deer	Coccidiosis	10-746
Florfenicol	Oral	Fish (finfish)	Bacterial infection	11-145
Strontium chloride	Immersion	Fish	Otolith marking	10-536
Sulfadimethoxine & ormetoprim	Premix	Fish	Bacterial infections	10-823
Carp Pituitary	Injectable	Fish (Various)	Spawning aid	9757
Oxytetracycline	Feed	Fish (Various)	Vibriosis	10-320
Erythromycin	Premix	Fish (Salmonids)	Bacterial kidney disease	6013
Lasalocid	Premix	Goats	Coccidiosis	10-872
Progesterone	CIDR	Goats	Estrus synchronization	11-389
Tulathromycin	Injection	Goats	Respiratory infection	11-512
Lasalocid	Premix	Pheasants	Coccidiosis	9096
Fenbendazole	Premix	Pheasants & partridges	Gapeworm & capillaria	10-062
Ivermectin	Injectable	Rabbits	Ear mits	9557
Progesterone	CIDR	Sheep	Estrus synchronization	10-321
Florfenicol	Injection	Sheep	Respiratory infections	10-958
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 2006

ADR	Date rec'd	Drug	Formulation	Species	Indication
1	Feb-82	Monensin	premix	goats	coccidiosis
2	Apr-82	Amprolium	premix	pheasants	coccidiosis
3	Nov-81	Monensin	premix	sheep	coccidiosis
4	Jun-82	Sulfadimethoxine/ ormetoprim	premix	catfish	bacterial infections
5	Apr-84	Thiabendazole	premix	pheasants	gapeworm
6	Nov-82	BHT	premix/ unspecified topical	fish	viral diseases
7	Oct-82	Various coccidiostats & antibiotics	——	rabbits	coccidiosis, pasteurellosis
8	Dec-82	Albendazole	oral suspension	goats	liver flukes
9	Dec-82	Lincomycin	premix	ducks	pasteurellosis
10	Dec-82	Penicillin	premix	ducks	erysipelas
11	Sep-81	Ivermectin	injectable	reindeer	warbles
12	Jul-83	Fenbendazole	oral suspension/ premix	goats	GI parasites
13	Jan-83	Monensin	premix	cattle	emphysema
14	Jan-83	Decoquinate	premix	sheep	coccidiosis
15	Oct-83	Oxytetracycline	premix	lobster	gaffkemia
16	Feb-83	Xylazine	injectable	goats	anesthesia
17	Jan-83	Ivermectin	injectable	goats	GI parasites
18	Jun-84	Chloramine-T	topical soluble powder	salmonids	bacterial gill disease
19	Dec-83	Oxytetracycline	premix	alligators	bacterial infection
20	Jul-84	Chloramine-T	topical soluble powder	catfish	bacterial infection
21	Dec-82	Albendazole	oral suspension	sheep	liver flukes
22	Aug-84	Penicillin	injectable	ducks	erysipelas
23	Apr-83	Lutalyse	injectable	goats	anestrus
24	Apr-83	Monensin	premix	goats	coccidiosis
25	May-83	Xylazine	injectable	cattle	anesthetic
26	Jun-83	Mebendazole	oral paste	goats	GI parasites
27	May-83	Spectinomycin	intramammary infusion	cattle	mastitis
28	Oct-83	Chloramine-T	topical soluble powder	salmonids	external bacterial infections
29	Oct-83	Lasalocid	premix	goats	coccidiosis
30	Oct-83	Bacitracin	premix	quail	ulcerative enteritis
31	Nov-83	Praziquantel	premix/ oral capsule	wild ducks, geese, mute swan	schistosomiasis
32	Dec-83	Ampicillin	oral bolus	goats	enteritis
33	Dec-83	Amoxicillin trihydrate	injectable	dairy goats (nonlactating)	bacterial pneumonia
34	Dec-83	Amoxicillin trihydrate	oral bolus	dairy goats (nonlactating)	bacterial enteritis
35	Dec-83	Amoxicillin trihydrate	oral bolus	dairy goats (nonlactating)	bacterial enteritis
36	Dec-83	Ampicillin	injectable	dairy goats (lactating)	bacterial pneumonia
37	Dec-83	Ampicillin	injectable	dairy goats (nonlactating)	bacterial pneumonia & enteritis
38	Dec-83	Ampicillin	oral bolus	dairy goats (nonlactating)	enteritis
39	Dec-83	Chlortetracycline	premix	dairy goats (nonlactating)	bacterial infections
40	Dec-83	Chlortetracycline	premix	dairy goats	bacterial pneumonia
41	Dec-83	Neomycin sulfate	oral soluble powder	dairy goats (nonlactating)	enteritis
42	Dec-83	Oxytetracycline	injectable (100 mg/ml)	dairy goats (nonlactating)	bacterial infections
43	Dec-83	Oxytetracycline	injectable	dairy goats (nonlactating)	bacterial pneumonia
44	Dec-83	Oxytetracycline	injectable (long acting)	dairy goats (nonlactating)	bacterial infections
45	Dec-83	Oxytetracycline	injectable (50 mg/ml)	dairy goats (nonlactating)	bacterial infections
46	Dec-83	Benzathine penicillin	injectable	dairy goats	bacterial pneumonia
47	Dec-83	Procaine Penicillin	injectable	dairy goats	bacterial infections
48	Dec-83	Sulfachloropyridazine	oral powder	dairy goats	enteritis
49	Dec-83	Sulfachloropyridazine	injectable	dairy goats	enteritis
50	Dec-83	Sulfabromomethazine	oral bolus	dairy goats	bacterial infections
51	Dec-83	Sulfachloropyridazine	oral bolus	dairy goats	enteritis
52	Dec-83	Sulfadimethoxine	oral drinking water solution	dairy goats	bacterial pneumonia
53	Dec-83	Sulfadimethoxine	oral bolus?	dairy goats	bacterial pneumonia
54	Dec-83	Sulfadimethoxine	oral powder	dairy goats	bacterial pneumonia
55	Dec-83	Sulfadimethoxine	oral powder	dairy goats	bacterial pneumonia

ADR	Date rec'd	Drug	Formulation	Species	Indication
56	Dec-83	Sulfaethoxypyridazine	injectable	dairy goats	bacterial infections
57	Dec-83	Sulfaethoxy- pyridazine	oral drinking water solution	dairy goats	bacterial infections
58	Dec-83	Sulfaethoxy- pyridazine	oral bolus	dairy goats	bacterial infections
59	Dec-83	Sulfamethazine	oral sustained release tablets	goats	bacterial pneumonia
60	Dec-83	Oxytetracycline	injectable	goats	enteritis
61	Dec-83	Tylosin	injectable	goats	bacterial pneumonia
62	Jan-84	Benzathine cloxacillin	intramammary infusion	dairy goats	mastitis
63	Jan-84	Benzathine cloxacillin (Dry-Clox)	intramammary infusion	dairy goats	mastitis
64	Jan-84	Cephapirin benzathine	intramammary infusion	dairy goats	mastitis
65	Jan-84	Novobiocin	intramammary infusion	dairy goats	mastitis
66	Jan-84	Novobiocin/ penicillin	intramammary infusion	dairy goats	mastitis
67	Jan-84	Hetacillin	intramammary infusion	goats	mastitis
68	Jan-84	Sodium cepharin	intramammary infusion	goats	mastitis
69	Jan-84	Sodium cloxacillin	intramammary infusion	goats	mastitis
70	Jan-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease
71	Jan-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease
72	Feb-84	Diquat	immersion	brown trout	bacterial gill disease
73	Feb-84	Furazolidone	premix	trout	furunculosis
74	Feb-84	Sulfamethazine	oral sustained release tablets	sheep	bacterial pneumonia
75	Feb-84	Dimethyl benzyl ammonium chloride	immersion	brown trout	bacterial gill disease
76	Feb-84	Ethoxyquin	premix	sheep	bittersweet poisoning
77	Mar-84	Clinoprost tromethamine??	injectable	sheep	breeding synchronization
78	Mar-84	Ivermectin		sheep	G.I. parasites
79	Mar-84	Lasalocid	premix	sheep	coccidiosis
80	Mar-84	Levamisole	Oral soluble powder	sheep	G.I. parasites
81	Mar-84	Monensin	premix	sheep	coccidiosis
82	Mar-84	Norgesterone	injectable	sheep	estrus synchronization
83	Mar-84	Oxytetracycline	injectable	sheep	bacterial pneumonia
84	Mar-84	Spectinomycin	injectable/oral soluble powder	sheep	colibacillosis
85	Mar-84	Tylosin	premix	sheep	Mycoplasma pneumonia
86	Mar-84	Progesterone	injectable	sheep	anestrus
87	Apr-84	Amoxicillin trihydrate	injectable	sheep	bacterial pneumonia
88	Apr-84	Ampicillin	injectable	sheep	bacterial pneumonia
89	Apr-84	Virginiamycin	premix	rabbits	bacterial infections
90	May-84	Monensin	premix	quail	coccidiosis
91	May-84	Erythromycin	premix	quail	chronic respiratory disease
92	May-84	Ipronidazole	oral	quail	blackhead
93	May-84	Isoxsuprine HCl	Oral tablets	horse	navicular disease
94	May-84	Di-N-Butyl Tin Oxide	immersion	channel catfish	tapeworms
95	May-84	Levamisole	Oral soluble powder	goats	G.I. parasites
96	May-84	Sulfadimethoxine /ormetoprim	premix	catfish	bacterial infections
97	May-84	Tricaine methanesulfonate	topical solution	salmonids	anesthetic
98	Aug-84	Levamisole	Oral soluble powder	sheep	G.I. parasites
99	Aug-84	Sulfaquinoxaline	premix	pheasants	coccidiosis
100	May-84	Mebendazole	oral soluble powder	goats	G.I. parasites
101	May-84	Methylene blue	injectable	cattle	nitrate poisoning
102	May-84	Erythromycin thiocyanate	premix	mink	enteritis
103	Aug-84	Griseofulvin	oral soluble powder	rabbits	ringworm
104	Aug-84	Monensin	premix	rabbits	coccidiosis
105	Aug-84	Procaine penicillin	injectable	rabbits	pasteurellosis
106	Aug-84	Azaperone	injectable	wild ungulates	immobilization
107	Sep-84	Ivermectin	injectable	rabbits	ear mites
108	Sep-84	Chlortetracycline	injectable	rabbits	pasteurellosis
109	Sep-84	Sulfadimethoxine /ormetoprim	premix	rabbits	hepatic coccidiosis
110	Sep-84	Ivermectin	Injectable	fox	ear mites

ADR	Date rec'd	Drug	Formulation	Species	Indication
111	Sep-84	Decoquinate	premix	goats	coccidiosis
112	Nov-84	Clorsulon	oral suspension	goats	liver flukes
113	Nov-84	Amprolium	oral soluble powder/ premix	quail	coccidiosis
114	Nov-84	Monensin	premix	quail	coccidiosis
115	Nov-84	Salinomycin	premix	quail	coccidiosis
116	Dec-84	Phenylbutazone	oral bolus?	sheep	arthritis
117	Dec-84	Lasalocid	premix	goats	coccidiosis
118	Jan-85	Tiamulin	premix	trout	red mouth disease
119	Jan-85	Sodium fluoride	premix	salmonids	bacterial kidney disease
120	Feb-85	Oxolinic acid	premix	salmonids	furunculosis, vibriosis
121	May-85	Amoxicillin	intramammary infusion	dairy goats	mastitis
122	May-85	Lasalocid	premix	rabbits	coccidiosis
123	Oct-85	Botram 75 W	soluble powder	bees	foulbrood
124	Jan-86	Fenbendazole	oral suspension	goats	GI parasites
125	Jul-85	Ivermectin	injectable	Am. bison	hypodermosis
126	Oct-85	Clorsulon	oral suspension	sheep	liver flukes
127	Nov-85	Fenbendazole	premix	bighorn sheep	lungworms
128	Dec-85	Amprolium	oral drinking water solution	swine (neonates)	coccidiosis
129	Jan-86	Levamisole	Oral soluble powder	quail	endoparasites
130	Jan-86	Chlorine dioxide	topical solution	salmonids	furunculosis, bacterial gill disease
131	Feb-86	Benzocaine	topical soluble powder	salmonids	anesthesia
132	Mar-86	Melatonin	premix	sheep	anestrus
133	Mar-86	Lactic acid	injectable	sheep (lambs)	chemical castration
134	Mar-86	Levamisole	oral soluble powder	goats	GI parasites
135	Jul-86	Erythromycin	premix	salmonids	bacterial kidney disease
136	Aug-86	Sulfadimethoxine /ormetoprim	premix	quail	coccidiosis
137	Aug-86	Sulfadimethoxine /ormetoprim	premix	chukar partridges	coccidiosis
138	Oct-86	Virginiamycin	premix	alligators	hatchling alligator syndrome
139	Nov-86	Ivermectin	injectable	cattle	ticks
140	Feb-87	Amprolium	oral soluble powder premix	rabbits	coccidiosis
141	Feb-87	Ivermectin	injectable	rabbits	ear mites
142	Feb-87	Oxytetracycline	premix	rabbits	bacterial infections
143	Jan-87	Lasalocid	premix	rabbits	coccidiosis
144	Sep-87	Morantel tartrate	premix	goats	GI parasites
145	Sep-87	Enrofloxacin	premix	salmonids	furunculosis
146	Sep-87	Enrofloxacin	premix	salmonids	bacterial kidney disease
147	Oct-87	Ivermectin	injectable/oral suspension	mink	GI parasites
148	Oct-87	Amprolium	oral soluble powder/ premix	mink	coccidiosis
149	Oct-87	Sulfathiazole	oral soluble powder	mink	bacterial enteritis
150	Oct-87	Sulfadimethoxine	wsp/tablets/ oral suspension	mink	coccidiosis, resp. and UT infections
151	Oct-87	Ivermectin	injectable/oral suspension	foxes	GI parasites
152	Oct-87	Amprolium	soluble powder/ premix	foxes	coccidiosis
153	Oct-87	Sulfathiazole	soluble powder	foxes	bacterial enteritis
154	Oct-87	Sulfadimethoxine	oral soluble powder/tablets/oral suspension	foxes	coccidiosis, resp. and UT infections
155	Oct-87	Ivermectin	injectable	fish	external crustacean and internal nematode parasites
156	Oct-87	Praziquantel	premix/ injectable	fish	cestodes and trematodes
157	Nov-87	Ivermectin	injectable	ranch foxes	ear mites
158	Nov-87	Tricaine methanesulfonate	topical soluble powder	striped bass	anesthesia
159	Nov-87	Sulfadimethoxine /ormetoprim	premix	striped bass	bacterial infections
160	Nov-87	Formalin	topical solution	striped bass	external protozoan parasites
161	Nov-87	Oxytetracycline	premix	striped bass	pasteurellosis
162	Mar-88	Fumagillin dicyclohexylamine	premix/ injectable	salmonids	proliferative kidney disease
163	Mar-88	Fenbendazole	premix	pheasants	gapeworm
164	Mar-88	Morantel tartrate	premix/oral bolus	sheep	GI parasites
165	Mar-88	Ceftiofur	injectable	sheep	bacterial pneumonia

ADR	Date rec'd	Drug	Formulation	Species	Indication
166	Mar-88	Ceftiofur	injectable	goats	bacterial pneumonia
167	Apr-88	Lincomycin/spectinomycin	oral soluble powder	quail	air sacculitis
168	Apr-88	Fenbendazole	oral soluble powder	quail	GI parasites
169	Jun-88	Formalin	oral soluble powder	penaeid shrimp	External protozoan parasites
170	Feb-89	Ceftiofur	injectable	sheep	bacterial pneumonia
171	Feb-89	Ceftiofur	injectable	goats	bacterial pneumonia
172	Feb-89	Zinc bacitracin	premix	rabbits	post-weaning enteritis
173	Mar-89	Ethylenedinitrilo tetraacetic acid copper	injectable	sheep	copper deficiency
174	Mar-89	Erythromycin	premix/ injectable	salmonids	bacterial kidney disease
175	Apr-89	Enrofloxacin	premix	American eels	Aeromonas salmonicida infections
176	May-89	Amoxicillin (keep w/ 33)	injectable	dairy goats (lactating)	bacterial pneumonia
177	May-89	Enrofloxacin	oral drinking water solution	rabbits	pasteurellosis
178	Sep-89	Spectinomycin	injectable/oral soluble powder	ducks	colibacillosis, salmonellosis
179	Dec-89	PD 127391 (fluoroquinolone)	oral drinking water solution	cockatiels	psittacosis
180	Oct-89	Ceftiofur	intrauterine	dairy cattle	metritis
181	Nov-89	Morantel tartrate	premix/oral bolus	sheep	GI parasites
182	Nov-89	Albendazole	premix/block	white tailed deer	meningeal worm
183	Nov-89	Metaclopramide	implant	cattle	fescue toxicosis
184	Apr-90	PD 117,596 (fluoroquinolone)	premix	salmonids	furunculosis
185	May-90	Fenbendazole	premix/feed block	white tailed deer	meningeal worm
186	May-90	Sodium carbonate peroxyhydrate	topical soluble powder	channel catfish	external protozoan parasites
187	May-90	Avermectin (Moxidectin)	biobullet implant	bighorn sheep	scabies, GI parasites, lungworm
188	May-90	Avermectin (Moxidectin)	biobullet implant	deer	GI parasites, external parasites
189	Jun-90	Sulfathiazole	premix	mink	bacterial pneumonia (Pseudomonas)
190	Jul-90	Ceftiofur	biobullet implant	bighorn sheep	bacterial pneumonia
191	Aug-90	Lasalocid	premix	chukar partridges	coccidiosis
192	Aug-90	Ethylene vinyl acetate copolymer	pellet bait binder	lobsters, crabs	bait binder
193	Oct-90	Sarafloxacin	premix	alligators	hatchling alligator syndrome
194	Nov-90	Cephapirin	intramammary infusion	dairy goats	mastitis
195	Nov-90	Ivermectin	premix	bighorn sheep	scabies
196	Feb-91	Ivermectin	pour-on	llamas	GI parasites
197	Feb-91	Ivermectin	pour-on	red deer	GI parasites and lungworm
198	Apr-91	Ceftiofur	injectable	rabbits	pasteurellosis
199	Mar-91	Enrofloxacin	soluble powder	penaeid shrimp	bacterial infections
200	Mar-91	Erythromycin	soluble powder/premix	penaeid shrimp	bacterial infections
201	Mar-91	Trichlorfon	soluble powder	channel catfish	insect predation
202	Feb-91	Ivermectin/ Clorsulon	injectable	llamas	GI parasites, liver flukes
203	Feb-91	Enrofloxacin	premix	striped bass	bacterial infections
204	Oct-91	Nitrofurazone	topical soluble powder	shrimp	bacterial infections
205	Oct-91	Copper	topical solution (concentrate)	shrimp	bacterial infections
206	Nov-91	Albendazole	premix/feed block	white tail deer	meningeal worm
207	Dec-91	Captan	topical soluble powder	sheep	club lamb fungus
208	Dec-91	Trifluralin	topical solution (concentrate)	shrimp	mycosis
209	Jan-92	Amoxicillin	premix	salmonids	furunculosis
210	Mar-92	Fenbendazole (216 active)	premix	red deer	G.I. parasites
211	Mar-92	Ivermectin	blocks	bighorn sheep	psoroptic mange
212	Apr-92	Metaclopramide	oral bolus	cattle	fescue toxicosis
213	Apr-92	Sarafloxacin	premix	striped bass	septicemia
214	Apr-92	Enrofloxacin	premix	hybrid striped bass	columnaris disease
215	Apr-92	Sarafloxacin	premix	channel catfish	enteric septicemia and motile Aeromonas septicemia
216	May-92	Fenbendazole	premix	fallow deer	GI parasites
217	May-92	Tylosin	soluble powder	honey bees	foul brood
218	Sep-92	Phenothiazine	block/pellet/ liquid	sheep, goats	GI parasites
219	Sep-92	N,N'-bis-(dichloroacetyl)-1-8 octane diamine	premix	timber wolves	antispermatogenic contraceptive
220	Nov-92	Oxytetracycline	premix	Chinook salmon	columnaris disease, vibriosis

ADR	Date rec'd	Drug	Formulation	Species	Indication
221	Nov-92	Oxytetracycline	premix	white sea bass	columnaris disease, vibriosis
222	Nov-92	Ivermectin	pour-on	American bison	GI parasites
223	Dec-92	Ceftiofur	injectable	goats	bacterial pneumonia
224	Dec-92	Procaine penicillin G	injectable	goats	bacterial pneumonia
225	Dec-92	Erythromycin	injectable	goats	bacterial pneumonia
226	Dec-92	Tylosin	injectable	goats	bacterial pneumonia
227	Dec-92	Sulfadimethoxine	injectable	goats	bacterial pneumonia
228	Jan-93	Ceftiofur	injectable	veal calves	respiratory infections
229	Jan-93	Zinc bacitracin	premix	veal calves	enteric disorders, feed efficiency
230	Jan-93	Ivermectin	sustained release oral bolus	reindeer	warbles
231	Feb-93	Copper sulfate	topical soluble powder	channel catfish	external protozoa
232	Mar-93	Human chorionic gonadotropin	injectable	striped bass, white bass, hybrid striped bass	spawning aid
233	Mar-93	Enrofloxacin	injectable	ducks	colibacillosis, salmonellosis, pasteurellosis (anatipestifer)
234	Jun-93	Luteinizing hormone releasing hormone analog	injectable	various fish	spawning aid
235	Jul-93	Lasalocid	premix	pheasant	coccidiosis
236	Jul-93	Clopidol	premix	pheasant	coccidiosis
237	Aug-93	Ivermectin	water	gamebirds	GI parasites
238	Sep-93	Formalin	topical soluble powder	Finfish and eggs	External fungal & protozoan parasites
239	Sep-93	Carp Pituitary	injectable	White Sturgeon	spawning aid
240	Sep-93	Potassium permanganate	topical soluble powder	White Sturgeon	External fungal & protozoan parasites
241	Sep-93	Oxytetracycline	premix	White Sturgeon	Internal bacterial
242	Sep-93	Oxytetracycline	immersion	White Sturgeon	External bacterial
243	Sep-93	Sarafloxacin	premix	White Sturgeon	Internal bacterial
244	Sep-93	Oxytetracycline	premix	various fish	otolith marking columnaris
245	Sep-93	Oxytetracycline	immersion	various fish	otolith marking
246	Sep-93	Tilmicosin phosphate	injectable	sheep	chronic respiratory
247	Oct-93	Diminazene aceturate	injectable	cattle	anaplasmosis piroplasmosis
248	Dec-93	Spectinomycin	injectable	veal calf	enteric colibacillosis
249	Aug-94	Oxytetracycline	injectable	veal calf	respiratory inf
250	Feb-94	Levamisole phosphate	injectable	bison	GI parasites Ostertagia
251	Aug-94	Ceftiofur	injectable	red deer	respiratory inf
252	Aug-94	Tilmicosin phosphate	injectable	veal calf	respiratory inf
253	Aug-94	Fenbendazole	premix	bison	GI parasites
254	Aug-94	Clopidol	premix	rabbit	coccidiosis
255	Jan-95	Salinomycin		rabbit	coccidiosis
256	Jan-95	Sulfadimethoxine & ormetoprim	premix	rabbit	coccidiosis
257	Mar-95	Oxytetracycline	soluble powder	lobster	gaffkemia
258	Mar-95	Progesterone	CIDR	sheep	estrus synchronization
259	Apr-95	Hydrogen peroxide	topical	various fish	bacterial gill disease
260	Apr-95	Hydrogen peroxide	topical	Atlantic salmon	sea lice
261	May-95	Ceftiofur	injectable	psittacine birds	gram-negative inf
262	Jun-95	Monensin	premix	rabbits	coccidiosis
263	Oct-95	Erythromycin	premix	hybrid striped bass	strep infections
264	Jan-96	Albendazole	premix	Emu	nem/trem/cest
265	Jan-96	Ceftiofur	injectable	Emu	bacterial infection
266	Jan-96	Ivermectin	injectable	Emu	nematodes, lice, mites
267	Jan-96	Sarafloxacin	WSP	Emu	bacterial infection
268	Jan-96	Sulfadimethoxine	soluble powder	Emu	bacterial infection & coccidiosis
269	Jan-96	Sarafloxacin	premix	catfish	Enteric septicemia
270	Mar-96	Amoxicillin	premix	hybrid striped bass	strep infections
271	Apr-96	Carp Pituitary	injectable	various fish	spawning aid
272	Jul-96	Sulfadimethoxine & ormetoprim	premix	pheasants	bacterial infection & coccidiosis
273	Jul-96	Nitarsone	premix	partridge	blackhead
274	Jul-96	Zoamix	premix	pheasants	growth, feed eff & coccidiosis
275	Jul-96	Ceftiofur sodium	injectable	llamas, alpaca, fallow deer	respiratory infection

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276	Jul-96	Fenbendazole	premix	Ostrich & Emu	nematodes
277	Jul-96	Potassium permanganate	topical	catfish	External ichthyophthirius multifilis
278	Aug-96	Monensin sodium	premix	pheasants & partridges	coccidiosis
279	Aug-96	Lasalocid	premix	pheasants	coccidiosis
280	Aug-96	Fenbendazole	premix	pheasants & partridges	gapeworm & capillaria
281	Aug-96	Deccox	premix	pheasants & partridges	coccidiosis
282	Aug-96	Chlortetracycline	premix	pheasants & partridges	bacterial infections
283	May-97	Oxytetracycline HCl	soluble powder	walleye (larval fish)	columnaris
284	Jun-97	MGA/GnRH	feed/ injectable	sheep	estrus synchronization
285	Nov-97	Oxytetracycline	feed	various fish	vibriosis
286	Nov-97	Oxytetracycline	feed	tilapia	strep infections
287	Feb-98	Ketamine	injectable	ostrich/emu	anesthetic
288	Feb-98	Xylazine	injectable	ostrich/emu	sedative
289	Feb-98	Enrofloxacin	WSP	ostrich/emu	bacterial infections
290	Feb-98	Trimethoprim/ Sulfadiazine	oral	ostrich/emu	bacterial infections
291	Jul-97	Ivermectin	oral bait	deer	GI parasites
292	Aug-97	Doxycycline	extruded feed	psittacines	Chlamydia
293	Mar-98	Imexon	Injectable	mink	Alleutian disease
294	Sep-98	Lasalocid	premix	deer	coccidiosis
295	Sep-98	Strontium Chloride	immersion	fish	otolith marking
296	Nov-98	Molybdate	injectable	sheep	copper toxicity
297	May-99	Triclabendazole	drench	deer/elk	liver flukes
298	May-99	Lasalocid	oral	goats	coccidiosis
299	Aug-99	Pirlimycin	intramammary	goats	mastitis
300	Aug-99	Moxidectin	topical	cage birds	mites face/airsac
301	Feb-00	Decoquinate	in milk	calves	cryptosporidiosis
302	Mar-00	Antimicrobials	immersion	shellfish	bacterial infection
303	Apr-00	Banamine	injection	veal calves	anti inflammatory
304	Apr-00	Neomycin 325	soluble powder	veal calves	bacterial enteritis
305	Apr-00	Chlortetracycline	soluble powder	veal calves	bacterial enteritis
306	Apr-00	Mu Se (selenium)	injection	veal calves	Se deficiency
307	Apr-00	Florfenicol	injection	veal calves	bacterial pneumonia
308	Apr-00	Micotil	injection	veal calves	bacterial pneumonia
309	Apr-00	Sulfamethoxazole/trimethoprim 960	oral - tablets	veal calves	bacterial infections
310	Apr-00	Cephalexin	oral	veal calves	bacterial infections
311	May-00	Lincomycin	soluble powder	bees	American Foulbrood
312	Jun-00	Imidocarb	injection	dairy cattle	anaplasmosis babesiosis
313	Oct-00	Sulfadimethoxine & ormetoprim	premix	fish	bacterial infections
314	Oct-00	Tripelennamine HCl	injection	veal calves	Antihistamine
315	Oct-00	Amikacin	injection	veal calves	Diarrhea
316	Oct-00	Sulfachlor- pyridazine	injection or oral	veal calves	Diarrhea
317	Oct-00	Levamisole phosphate	injection	veal calves	GI parasites
318	Oct-00	Penicillin	injection	veal calves	bacterial infections
319	Oct-00	Chlortetracycline	oral	veal calves	respiratory infections
320	Oct-00	Tylosin	injection	veal calves	respiratory infections
321	Oct-00	Apramycin	oral	veal calves	Diarrhea
322	Oct-00	Sulfadimethoxine	injection or oral	veal calves	respiratory infections
323	Oct-00	Various products	various	veal calves	various
324	Jan-01	Progesterone	CIDR	goats	estrus synchronization
325	Jul-01	Florfenicol	injection	sheep	respiratory infections
326	Jul-01	Florfenicol	injection	sheep	foot rot
327	Jul-01	Florfenicol	injection	goats	respiratory infections
328	Jul-01	Florfenicol	injection	goats	foot rot
329	Oct-01	Florfenicol	injection	veal calves	respiratory infections
330	Oct-01	Apitol	patties	honey bees	Varroa mites

ADR	Date rec'd	Drug	Formulation	Species	Indication
331	Mar-02	Arecoline (Cestolin)	oral tablets	gamebirds, pet birds, cocks	Tapeworms, ascarids, trichinosis
332	Oct-02	Oxytetracycline	Oral	abalone	withering syndrome
333	Dec-02	Florfenicol	Oral	shrimp	necrotizing pancreatitis
334	Jun-03	Florfenicol	Oral	finfish	bacterial infection
335	Mar-05	Ovaprim (GnRHa & Domperidone)	Injectable	ornamental fish	spawning aid
336	Mar-05	Metomidate	Injectable	ornamental fish	anesthetic
337	Jan-06	Progesterone	CIDR	goats	estrus synchronization
338	Apr-06	Ceftiofur hydrochloride	Intramammary	goats	mastitis
339	May-06	tulathromycin	Injection	sheep	respiratory infections
340	May-06	tulathromycin	Injection	goats	respiratory infections
341	Sep-06	Melatonin	Implant	sheep	reproductive aid
342	Oct-06	Moxidectin	Oral	goats	Internal parasites