

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
<p>1. An animal drug request is filed with the one of the four Regional Animal Drug Coordinators or the National Coordinator.</p> <p>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.</p> <p>3. Approval of new projects by the Animal Drug Technical Committee.</p>	<p>4. Send to the Regional Animal Drug Coordinator to initiate work with an investigator.</p> <p>5. Develop and send protocols to FDA/CVM and the drug company for review.</p> <p>6. Provide funding to the investigator to initiate studies.</p> <p>7. Conduct studies under Good Laboratory Practices (GLPs):</p> <ol style="list-style-type: none"> 1. Efficacy 2. Target animal safety 3. Human food safety 4. Environmental safety <p>8. Prepare Environmental Impact Assessment Statements.</p>	<p>9. Prepare study report for FDA (investigator with assistance from the Regional Animal Drug Coordinator).</p> <p>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.</p> <p>11. Regional Animal Drug Coordinator finalizes report and submits it to FDA/CVM.</p>	<p>12. FDA/CVM prepares Public Master File containing summaries of the study reports.</p> <p>13. FDA/CVM formally reviews the Public Master File.</p> <p>14. FDA/CVM publishes the Public Master File in the <i>Federal Register</i>.</p> <p>15. Pharmaceutical company references the Public Master File and adds claim to existing label.</p>

Table 2. Federal and Nonfederal NRSP-7 Funding by Year (in thousands of dollars)

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	60%
1993	\$464	\$212	\$0.3	\$0.1	46%
1994	\$611	\$158	\$0	\$7	27%
1995	\$550	\$84	\$0	\$0	15%
1996	\$550	\$192	\$0	\$0	35%
1997	\$550	\$357	\$0	\$0	65%
1998	\$550	\$105	\$97	\$0	37%
1999	\$550	\$317	\$10	\$7	61%
2000	\$550	\$349	\$10	\$0	65%
2001	\$549	\$87	\$39	\$0	23%
2002	\$588	\$138	\$30	\$0	29%
2003	\$588	\$138	nc	nc	23%
Total =	\$9,116	\$2,558	\$226	\$27	

nc = not computed

Table 3. Public Master Files (PMF) Published and New Animal Drug Approvals (NADA) Completed by NRSP-7

Drug	Formulation	Species	Indication	Firm
Albendazole	Oral suspension	Goats	Liver flukes	Pfizer
Amoxicillin	Injectable	Sheep	Respiratory disease	Pfizer
Amprolium	Premix	Pheasants	Coccidiosis	Merial
Bacitracin	Premix	Quail	Ulcerative enteritis	Alpharma
Ceftiofur	Injectable	Goats	Bacterial pneumonia	Pharmacia
Ceftiofur	Injectable	Sheep	Bacterial pneumonia	Pharmacia
Clorsulon	Oral suspension	Goats	Liver flukes	Merial
Decoquinat	Premix	Goats	Coccidiosis	Alpharma
Decoquinat	Premix	Sheep	Coccidiosis	Alpharma
Fenbendazole	Premix	Bighorn sheep	Lungworms	Intervet
Fenbendazole	Oral suspension	Goats	GI parasites	Intervet
Formalin	Topical soluble powder	Finfish and eggs	External fungal/protozoan parasites	Argent
Formalin	Oral soluble powder	Penaeid shrimp	External protozoan parasites	Argent
Ivermectin	Injectable	American bison	Hypodermosis	Merial
Ivermectin	Injectable	Fox	Ear mites	Merial
Ivermectin	Injectable	Goats	GI parasites	Merial
Ivermectin	Injectable	Reindeer	Warbles	Merial
Lasalocid	Premix	Chukar partridges	Coccidiosis	Alpharma
Lasalocid	Premix	Rabbits	Coccidiosis	Alpharma
Levamisole	Oral soluble powder	Goats	G.I. parasites	Schering
Monensin	Premix	Quail	Coccidiosis	Elanco
Morantel tartrate	Premix	Goats	GI parasites	Phibro
Oxytetracycline	Premix	Lobster	Gaffkemia	Phibro
Oxytetracycline	Injectable	Sheep	Bacterial pneumonia	Pfizer
Oxytetracycline	Immersion	Various fish	Otolith marking	Pfizer
Salinomycin	Premix	Quail	Coccidiosis	Alpharma
Sulfadimethoxine/ormetoprim	Premix	Catfish	Bacterial infections	Alpharma
Sulfadimethoxine/ormetoprim	Premix	Chukar partridges	Coccidiosis	Alpharma
Thiabendazole	Premix	Pheasants	Gapeworm	Merial
Tilmicosin phosphate	Injectable	Sheep	Chronic respiratory infections	Elanco

Table 4. NRSP-7 Active Projects

Drug	Formulation	Species	Indication	Firm
Carp Pituitary	Injectable	Various fish	Spawning aid	Stoller fisheries
Erythromycin	Premix	Salmonids	Bacterial kidney disease	Bimeda
Fenbendazole	Premix	Pheasants & partridges	Gapeworm & capillaria	Intervet
Florfenicol	Injectable	Sheep	Respiratory infections	Schering
Florfenicol	Injectable	Veal calves	Respiratory infections	Schering
Hydrogen peroxide	Topical	Various fish	Bacterial gill disease	Eko Nobel
Imidocarb	Injectable	Dairy cattle	Anaplasmosis babesiosis	Schering
Ivermectin	Injectable	Rabbits	Ear mites	Merial
Lincomycin	Soluble powder	Bees	American Foulbrood	Pharmacia
Oxytetracycline	Feed	Various fish	Vibriosis	Phibro
Progesterone	CIDR	Sheep	Estrus synchronization	Pharmacia
Strontium Chloride	Immersion	Fish	Otolith marking	Western Chemical
Sulfadimethoxine & ormetoprim	Premix	Fish	Bacterial infections	Alpharma
Tilmicosin phosphate	Injectable	Veal calf	Respiratory infections	Elanco
Tylosin	Soluble powder	Honey bees	foul brood	Elanco

Table 5. 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
Nitarson	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 multifiliis
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