

Minor Use Animal Drug Program NRSP-7

January 21, 2010

Ms. Rubie G. Mize
Assistant to the Executive Director
NERA
USDA-BARC-West Bldg. 003 Room 214
10300 Baltimore Avenue
Beltsville, MD 20705-2350



Dear Ms. Mize:

Attached please find the Appendix F budget request summary for NRSP-7 for 2010-2011. Also included are the FY 2010-2011 estimated budget summaries of funding that NRSP-7 receives from other sources including FDA/CVM, individual college and state funding, and stakeholder industry support. The multi-state funds that NRSP-7 receives will be used to partially cover the salaries of support personnel in the four regions and the National Coordinator's office located in the Cornell Technology Park. Moreover, these multi-state funds represent 51% of the Program's financial support and nearly 90% of its research efforts.

In accordance with the focus of NRSPs, the mission of the NRSP-7 Minor Use Animal Drug Program is:

- i. To identify animal drug needs for minor species and minor uses in major species,
- ii. To generate and disseminate data for safe and effective therapeutic applications, and
- iii. 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.

Globalization of food markets has allowed countries with less stringent animal drug approval requirements to dominate our honey, farmed shrimp and fish, sheep, goat, venison, and game bird production industries.

- i. Sixty-six percent of the honey consumed in the US is imported and half of that honey comes from China;
- ii. Nearly 90% of the commercially farmed shrimp are imported; and
- iii. Thirty-three percent of the lamb, 50% of the goat meat, and 82% of venison consumed in the US comes from Australia and New Zealand.

Agricultural production of fish, game birds, sheep, goats, honeybees and deer is critically important to numerous regional economies in the United States (**see Table 1**). This diverse aggregate of minor species represents approximately **\$4.4 billion** in food and fiber farm gate revenues annually. Processing, use, and export of minor species food and fiber products represent an additional **\$34 billion** economic impact to the US. These revenues are seriously threatened by the lack of appropriate drugs to treat these important species.

Since the first drug approval in 1984 under the former IR-4 program, NRSP-7 has been responsible for generating 35 Public Master File (PMF) publications in the *Federal Register*, an average of 1.3 per year during its 28 years of funding. The mean total expenditure per completed research for a drug approval or publication of a PMF over this time period was \$440,000. Average federal expenditures per completed research for a drug approval or publication of a PMF was \$335,000. Over the last ten years, however, the cost for NRSP-7 to provide the data necessary to support a single label claim has risen three-fold to approximately \$1.4 million. This increase is due to (1) more sophisticated analytical procedures for residue analysis, (2) the need to conduct all studies under Good Laboratory Practices and auditing of projects, (3) more expensive environmental assessments, and (4) the expanded scope of requests to additional species including veal and deer. Compared to an average investment of the pharmaceutical industry of \$4 to \$10 million for adding a label claim to an existing veterinary drug, expenses for data generated for additional label claims by the NRPS-7 program are approximately 14 to 35% of pharmaceutical industry costs. With NRSP-7 current level of funding and cost per drug approval of \$1.4 million, the expected time for achieving a drug approval is nearly three years. Thus, it is anticipated that NRSP-7 will achieve one to two approvals over the next five years.

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.

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 17 current active projects, the backlog of projects represents a research commitment stretching over several decades.

In 2009 data from the NRSP-7 Minor Use Animal Drug Program was used in support of the FDA approval of progesterone inserts for estrus synchronization in sheep (PMF 5947 March 20, 2009). Finally, during 2008 the regional coordinators published six articles in peer-reviewed journals disseminating information relevant to the program's mission.

The Minor Use Animal Drug Program has greatly impacted the various minor species (**Table 1**). Without this program, American minor species producers would simply not have sufficient safe and effective products to keep their livestock healthy.

Please address your question to me at the email address listed.

Sincerely,

John G. Babish, Ph.D.

National Coordinator, Minor Use Animal Drug Program/NRSP-7

cc: John Baker, Chair, NRSP-7 Administrative Advisors

Administrative Advisors

NRSP-7 Regional Coordinators

Attachments

Table 1. . Minor Species Industries, Leading States, Farm Gate Value and Economic Impact in the US.

Appendix F: NRSP BUDGET REQUESTS SUMMARY

Table 1. Minor Species Industries, Leading States, Farm Gate Value and Economic Impact in the US.

INDUSTRY	LEADING STATES	US FARM GATE VALUE [\$M]	US ECONOMIC IMPACT [\$M]	NRSP-7 ACTIVITY	
				APPROVALS	ACTIVE
Game Bird	TX, NC, PA, KS, WI, NY, IL, SD, FL, MN, IA, GA, MS, IN & AL.	\$830	\$5,000	Chukar partridges Sulfadimethoxine/Ormetoprim Lasalocid Pheasants Amprolium Thiabendazole Quail Salinomycin Bacitracin Monensin	Pheasants Lasalocid Sulfadimethoxine/Ormetoprim Fenbendazole
Rabbits	CA, GA, OH, PA, & TX	\$20	\$831	Laslocid	Ivermectin
Honey Bees	ND, CA, SD, FL, MT, MN, TX, & WI.	\$153	\$16,000	Tylosin	Lincomycin
Cervid	TX, PA, OH, FL, LA, IA, & KS	\$894 (farming) \$757 (hunting)	\$3,000	Bison Ivermectin Reindeer Ivermectin	Deer Lasalocid Fallow Deer Fenbendazole
Meat Goats	TX, TN, CA, GA, OK, NC, KY, MO, FL, & AL	\$173.2 \$189 (breeding)	\$1,039	Fenbendazole Monensin Decoquinatate Morantel tartrate	Lasalocid Tulathromycin CIDR (progesterone)
Dairy Goats	TX, OH, NY, PA, WI, WA, IN, CA, MD, MN, MI, FL, & KS.	\$58.3 \$14.8 (export)	\$439	Fenbendazole Monensin Decoquinatate Morantel tartrate	Lasalocid Ceftiofur HCl (Intramammary) Tulathromycin CIDR (progesterone)
Sheep	TX, CA, WY & CO	\$750	\$4,500	Bighorn Sheep Fenbendazole Sheep Decoquinatate Ceftiofur Tilmicosin phosphate CIDR (progesterone)	Sheep Tulathromycin
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	Catfish Sulfadimethoxine/Ormetoprim Finfish Formalin Oxytetracycline Hydorgen peroxide Lobster Oxytetracycline	Fish Sulfadimethoxine/Ormetoprim Florfenicol Erythromycin Carp pituitary Strontium chloride Oxytetracycline

Total = \$4,407 Total = \$33,848

Appendix F: NRSP BUDGET REQUESTS SUMMARY

(01 October 1, 2009 – September 30, 2014)

NRSP – 7 Minor Use Animal Drugs

A National Agricultural Program for Minor Use Animal Drugs

MRF FUNDING

DESCRIPTION	Proposed FY 1 FY 2010-2011		Proposed FY 2 FY 2011-2012		Proposed FY 3 FY 2012-2013		Proposed FY 4 FY 2013-2014		Proposed FY 5 FY 2014-2015	
	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE
SALARIES^(a)	153,800	5.0	153,800	5.0	153,800	5.0	153,800	5.0	153,800	5.0
FRINGE BENEFITS	49,536		49,536		49,536		49,536		49,536	
WAGES										
TRAVEL^(b)	10,085		10,085		10,085		10,085		10,085	
SUPPLIES^(c)	107,088		107,088		107,088		107,088		107,088	
MAINTENANCE^(d)	2,096		2,096		2,096		2,096		2,096	
EQUIPMENT/ CAPITAL IMPROVEMENT^(e)	2,395		2,395		2,395		2,395		2,395	
TOTAL	325,000	5.0	325,000	5.0	325,000	5.0	325,000	5.0	325,000	5.0

^(a)Includes part-time salaries for National Coordinator, and support staff in Northeast, Southern and Western Regions.

^(b)Travel for Technical Committee to attend biannual meetings, GLP monitoring of studies and final reports.

^(c)Funding of Target Animal Safety, Human Food Safety and Residue Depletion studies.

^(d)Maintenance contracts for analytical equipment.

^(e)Leasing of analytical equipment.

OTHER SOURCES OF FUNDING

Please check one of the following: Industry Federal Agencies Grants/Contracts SAESs
 US Food and Drug Administration/Center for Veterinary Medicine
 Other (please list): _____

DESCRIPTION	Proposed FY 1 FY 2010-2011		Proposed FY 2 FY 2011-2012		Proposed FY 3 FY 2012-2013		Proposed FY 4 FY 2013-2014		Proposed FY 5 FY 2014-2015	
	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)
SALARIES AND WAGES	109,118	1.0	109,118	1.0	109,118	1.0	109,118	1.0	109,118	1.0
FRINGE BENEFITS	43,452		43,452		43,452		43,452		43,452	
TRAVEL	2,200		2,200		2,200		2,200		2,200	
MATERIALS AND SUPPLIES	7,370		7,370		7,370		7,370		7,370	
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
RESEARCH										
GOV'T HOLD BACK										
TOTAL	162,140		162,140		162,140		162,140		162,140	

(a) Salary, benefits, materials and supplies for full-time FDA/CVM liaison to the NRSP-7 program provided by FDA/CVM.

OTHER SOURCES OF FUNDING

Please check one of the following: Industry Federal Agencies Grants/Contracts SAESs

■ Other (please list): College and State Funding

DESCRIPTION	Proposed FY 1 FY 2010-2011		Proposed FY 2 FY 2011-2012		Proposed FY 3 FY 2012-2013		Proposed FY 4 FY 2013-2014		Proposed FY 5 FY 2014-2015	
	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)	Dollars	FTE ^(a)
SALARIES AND WAGES	41,470	0.4	41,470	0.4	41,470	0.4	41,470	0.4	41,470	0.4
FRINGE BENEFITS	27,632		27,632		27,632		27,632		27,632	
TRAVEL										
MATERIALS AND SUPPLIES										
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
RESEARCH										
GOV'T HOLD BACK										
TOTAL	69,102	0.4	69,102	0.4	69,102	0.4	69,102	0.4	69,102	0.4

(a) Salary and benefits for four regional coordinators to the NRSP-7 program provided by individual college and state funding.

OTHER SOURCES OF FUNDING

Please check one of the following: **Industry^(a)** **Federal Agencies** **Grants/Contracts** **SAESs**

Other (please list): _____

DESCRIPTION	Proposed FY 1 FY 2010-2011		Proposed FY 2 FY 20011-2012		Proposed FY 3 FY 2012-2013		Proposed FY 4 FY 2013-2014		Proposed FY 5 FY 2014-2015	
	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE
SALARIES AND WAGES	41,250	0.25	41,250	0.25	41,250	0.25	41,250	0.25	41,250	0.25
FRINGE BENEFITS	11,962		11,962		11,962		11,962		11,962	
TRAVEL										
MATERIALS AND SUPPLIES	31,229 ^(b)		31,229 ^(b)		31,229 ^(b)		31,229 ^(b)		31,229 ^(b)	
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
RESEARCH	(c)		(c)		(c)		(c)		(c)	
TOTAL	84,441		84,441		84,441		84,441		84,441	

(a) Includes personnel from the veterinary pharmaceutical and animal production industries needed to review protocols, data submissions, change label claims and file amended animal drug applications. Companies specifically involved with NRSP-7 include Pfizer, Biomedica, Intervet, Schering and Alpha.

(b) For the years 1999 to 2008, the average MATERIALS AND SUPPLIES contribution from industry was \$31,229. MATERIALS AND SUPPLIES included total costs directly attributable to carrying out the grant including storage and office space rental, supplying drugs, analytical support or animals for efficacy, safety or residue depletion studies.

(c) Cooperation with pharmaceutical companies to sponsor animal drug research projects is vital to the NRSP-7 program. The major contribution to the program is the cost borne by the pharmaceutical industry for the approval of drugs for a major species, estimated at approximately \$20 million or more per approved drug [Ringer RK, Miller LR, Saylor WW. 1999. Minor-use animal drug program--a national agricultural program to approve animal drugs for minor species and uses. *J Am Vet Med Assoc* 214: 1636-7].