MINOR USE ANIMAL DRUG PROGRAM
NRSP-7

January 16, 2012

Ms. Christina Hamilton
NCRA Assistant Director and NIMSS System Administrator
212D Agricultural Hall
1450 Linden Dr.
Madison, WI 53706-1562

Dear Ms. Hamilton:

Attached please find the NRSP-7/Minor Use Animal Drug Program (NRSP-7/MUADP) Appendix F budget request summary for 2012-2013. Also included are the FY2012-2013 estimated budget summaries for funding that NRSP-7/MUADP receives from other sources including the Food and Drug Administration Center for Veterinary Medicine (FDA/CVM), individual college and state funding, and stakeholder industry support. While these multi-state funds represent just 37% of the Program's total financial assistance of $882,000, they afford approximately 85% of its direct research support. As such they are indispensible to the program's contribution to its stakeholders.

In addition to supporting the research of the Program, 30% of the multi-state funds that NRSP-7/MUADP receives will be used to partially cover the salaries of support personnel in three regions and the National Coordinator's office located in the Cornell Technology Park.

In accordance with the focus of NRSPs, the mission of the NRSP-7/MUADP 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/MUADP functions through the coordination of efforts among animal producers, pharmaceutical manufacturers, FDA/CVM, United States Department of Agriculture/National Institute of Food and Agriculture (USDA/NIFA), 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 goat, sheep, venison, and game bird industries as well as honey, and farmed shrimp and fish production.

- Half of the goat meat, 33 percent of the lamb, and 82 percent of venison consumed in the US comes from Australia and New Zealand;
- Nearly 70 percent of the honey consumed in the US is imported and half of that honey comes from China; and
- Over 90 percent of the commercially farmed shrimp are imported.

Agricultural production of goats, sheep, deer, game birds, honey, crop pollination and aquaculture is critically important to numerous regional economies in the United States (**Table 1**). This diverse aggregate of minor species represents approximately **$4.8 billion** in food and fiber farm gate revenues annually. Processing, use, and export of minor species food and fiber products represent an additional **$36.6 billion** economic impact to the U.S. These revenues are seriously threatened by the lack of appropriate drugs to treat diseases in these important species.

Since the first drug approval in 1984 under the former IR-4 program, NRSP-7/MUADP has been responsible for generating **43 New Animal Drug Applications (NADA)** and **Public Master Files**

(PMF), an average of 1.4 per year during its 30 years of funding. The mean total expenditure per completed research for a drug approval or publication of a PMF over this time period was $460,000. Average federal expenditures per completed research for a drug approval or publication of a PMF was $293,000. Over the last ten years, however, the cost for NRSP-7/MUADP to provide the data necessary to support a single label claim has risen nearly ***eight-fold*** to approximately ***$3.5 million***. This increase is due to (1) more sophisticated new 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 $10 to $25 million for adding a label claim to an existing veterinary drug, expenses for data generated for additional label claims by the Program are approximately 10 to 35% of pharmaceutical industry costs. With NRSP-7/MUADP current level of funding and cost per drug approval of $3.5 million, the expected time for achieving a single drug approval from protocol development to publication of PMF is over six years. By maintaining prudent overlapping scheduling of projects, however, it is anticipated that NRSP-7/MUADP will achieve one to two approvals over the next five years.

Prioritization of Projects:

The process for selection of drugs for testing in NRSP-7/MUADP is initiated by the filing of an Animal Drug Request (ADR) form by any group or individual associated with specialty animal production or research. Representatives of such groups include, animal producers or their representative organizations, pharmaceutical manufacturers, university faculty and veterinarians. This ADR request form can be submitted online at www.NRSP7.org or through any of the four Regional Drug Coordinators, the National Coordinator, and FDA/CVM liaison. Once received, the ADR is assigned a unique ADR number and included in the master ADR listing maintained at FDA/CVM, the National Coordinator's headquarters and at www.NRSP7.org.

During the spring annual meeting the NRSP-7/MUADP Technical Committee and representatives of the Stakeholder Advisory Committee (SAC) review the current projects and consider new ADR for funding. Each newly received ADR is then evaluated by the Technical Committee and SAC according to established criteria that include (1) availability of a pharmaceutical manufacturing sponsor, (2) major species approval, (3) microbial resistance concerns, (4) significance to the animal industry, (5) cost of developing the necessary data, and (6) food safety implications. ADR requests that meet these criteria are considered as potential projects. The number of highest priority projects is currently 40.

To date 352 drug requests have been submitted to the NRSP-7/MUADP for the development of data in support of the submission of an NADA. Currently there are 22 active research projects involving nine animal species and 11 different drugs. While funds are limited, it is necessary to maintain a number of active projects as sponsors may withdraw support for studies or new federal regulations may remove drugs from consideration with little or no notice. Much of the work on these studies involves background work such as protocol development or report writing followed by FDA/CVM review and approval of these protocols or reports. While this aspect of work necessary for an FDA/CVM drug approval is time consuming, it does not exhaust research category funding.

Impact Statements Relative to NRSP-7/MUADP Mission:

1. Since its inception in 1982, more than $12.6 million has been allocated to the program through Federal funding. In return NRSP-7/MUADP has generated publication of 36 PMF in the *Federal Register*. These PMF have, in turn, supported FDA/CVM approvals for 43 drugs for use in minor food species or for minor uses in major species. Compared to an average investment of the

pharmaceutical industry of $10 to $25 million for adding a label claim to an existing veterinary drug, expenses for data generated for additional label claims by the NRSP-7/MUADP program are approximately 10 to 35% of pharmaceutical industry costs.

2. To date 352 drug requests have been submitted to the NRSP-7/MUADP for the development of data in support of the submission of NADA or supplemental NADA. Currently there are 22 active research projects involving nine animal species and 11 different drugs.

3. The Environmental Assessment study data for erythromycin in salmonids INAD I-00613 were accepted by FDA/CVM on 1/12/11.

4. On 2/11/11, the tissue residue depletion study of Nuflor Gold in sheep submitted by NRSP-7/MUADP was accepted by FDA/CVM.

5. The Effectiveness Study of lasalocid in pheasants submitted by NRSP-7/MUADP to FDA/CVM on 7/1/10 was deemed complete by the agency on 3/25/11.

6. On July 1, 2011, the FDA/CVM published the availability of effectiveness, target animal safety, microbial food safety, residue chemistry, and environmental impact data that may be used in support of a NADA or supplemental NADA for use of lincomycin hydrochloride water soluble powder for the control of American foulbrood (*Paenibacillus larvae*) in honey bees. The NRSP-7/MUADP compiled the data, contained in PMF 5988.

7. On 8/12/11, the FDA/CVM approved the Human Food Safety sections of the CIDR-goat study submitted 11/18/10.

8. Also in 2011, data from NRSP-7/MUADP was used in support of the FDA/CVM approval of Chloramine-T safety and efficacy studies for control of bacterial gill disease in freshwater-reared salmonids. This formulation is used by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease.

Agricultural production of minor species is critically important to numerous regional economies in the U.S. This diverse aggregation of minor species represents approximately $4.8 billion in food and fiber farm gate revenues annually. Processing, use, and export of minor species food and fiber products represent an additional $36.6 billion economic impact to the U.S. Through a productive NRSP-7/MUADP, producers and veterinarians will continue to have the necessary information to prevent disease-related losses, to reduce pain and suffering in important species, and avoid contamination of our foods with drug residues.

Please address your question to the John Baker or John Babish at the email addresses listed.

Sincerely,

John Baker
Chair, NRSP-7 Administrative Advisors
Baker@anr.msu.edu

John G. Babish, Ph.D.
National Coordinator,
NRSP-7/Minor Use Animal Drug Program
jgb7@cornell.edu

cc: Administrative Advisors
NRSP-7 Regional Coordinators

Attachments
Table 1. U.S. Economic Impact of NRSP-7/MUADP Activity.
Appendix F: NRSP-7/MINOR USE ANIMAL DRUG PROGRAM BUDGET REQUESTS SUMMARY

Table 1. U.S. Economic Impact of NRSP-7/MUADP Activity.

Industry	Leading States	US Farm Gate Value [$M]	US Economic Impact [$M]	NRSP-7 Activity	
				Approvals	Active
Game Birds Pheasant Quail Chukar partridge	TX, NC, PA, KS, WI, NY, IL, SD, FL, MN, IA, GA, MS, IN & AL.	$897	$5,401	**Chukar partridges** Sulfadimethoxine/Ormetoprim Lasalocid **Pheasants** Amprolium Thiabendazole **Quail** Salinomycin Bacitracin Monensin	**Pheasants/Quail/Partridge** Lasalocid Fenbendazole
Rabbits	CA, GA, OH, PA, & TX	$21.6	$898	Laslocid	Ivermectin
Honey Bees	ND, CA, SD, FL, MT, MN, TX, & WI.	$166	$17,284	Tylosin Lincomycin	
Cervid	TX, PA, OH, FL, LA, IA, & KS	$966 (farming) $817 (hunting)	$3,241	**Bison** Ivermectin **Reindeer** Ivermectin	**Deer** Lasalocid **Fallow Deer** Fenbendazole
Meat Goats	TX, TN, CA, GA, OK, NC, KY, MO, FL, & AL	$187 $205 (breeding)	$1,123	Fenbendazole Monensin Decoquinate Morantel tartrate	Lasalocid Tulathromycin CIDR (progesterone)
Dairy Goats	TX, OH, NY, PA, WI, WA, IN, CA, MD, MN, MI, FL, & KS.	$63.0 $16.0 (export)	$474	Fenbendazole Monensin Decoquinate Morantel tartrate	Lasalocid Ceftiofur HCl (Intramammary) Tulathromycin CIDR (progesterone)
Sheep	TX, CA, WY & CO	$810	$4,861	**Bighorn Sheep** Fenbendazole **Sheep** Decoquinate Ceftiofur Tilmicosin phosphate CIDR (progesterone)	**Sheep** Tulathromycin Florfenicol (Nuflor) Florfenicol (Nuflor Gold)
Catfish/Aquaculture	**Catfish** MS, AK, AL, & LA **Trout** WA, WI, PA, ID, NC, OR, NY, CA, & CO	Catfish $518 Trout $94.6	$3,111 $172	**Catfish** Sulfadimethoxine/Ormetoprim Florfenicol **Finfish** Formalin Oxytetracycline hydrochloride Hydorgen peroxide Florfenicol Chloramine T **Lobster** Oxytetracycline dihydrate	**Fish** Sulfadimethoxine/Ormetoprim Erythromycin Carp pituitary Strontium chloride Oxytetracycline Florfenicol Povidone-iodine solution
		Total = $4,761	**Total =$36,564**		

Appendix F: NRSP-7/MINOR USE ANIMAL DRUG PROGRAM 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 2012-2013**		**Proposed FY 2 FY 2013-2014**		**Proposed FY 3 FY 2014-2015**		**Proposed FY 4 FY 2015-2016**		**Proposed FY 5 FY 2016-2017**	
	Dollars	**FTE**	**Dollars**	**FTE**	**Dollars**	**FTE**	**Dollars**	**FTE**	**Dollars**	**FTE**
SALARIES[a]	76,900	2.5	76,900	2.5	76,900	2.5	76,900	2.5	76,900	2.5
FRINGE BENEFITS	24,768		24,768		24,768		24,768		24,768	
WAGES										
TRAVEL [b]	5,000		5,000		5,000		5,000		5,000	
RESEARCH SUPPLIES[c]	213,841		213,841		213,841		213,841		213,841	
MAINTENANCE[d]	3,096		3,096		3,096		3,096		3,096	
EQUIPMENT/ CAPITAL IMPROVEMENT [e]	1,395		1,395		1,395		1,395		1,395	
TOTAL	325,000	2.5	325,000	2.5	325,000	2.5	325,000	2.5	325,000	2.5

[a]Includes part-time salaries for National Coordinator, and support staff in Northeast, Southern and Western Regions.
[b]Travel for 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 2012-2013		Proposed FY 2 FY 2013-2014		Proposed FY 3 FY 2014-2015		Proposed FY 4 FY 2015-2016		Proposed FY 5 FY 2016-2017	
	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]
SALARIES AND WAGES	204,330	1.5	204,330	1.5	204,330	1.5	204,330	1.5	204,330	1.5
FRINGE BENEFITS	81,366		81,366		81,366		81,366		81,366	
TRAVEL	4,123		4,123		4,123		4,123		4,123	
MATERIALS AND SUPPLIES	8,740		8,740		8,740		8,740		8,740	
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
RESEARCH										
GOV'T HOLD BACK										
TOTAL	298,558	1.5	298,558	1.5	298,558	1.5	298,558	1.5	298,558	1.5

(a) Salary, benefits, materials and supplies for full-time FDA/CVM liaison and assistant 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 2012-2013		Proposed FY 2 FY 2013-2014		Proposed FY 3 FY 2014-2015		Proposed FY 4 FY 2015-2016		Proposed FY 5 FY 2016-2017	
	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]	Dollars	FTE[(a)]
SALARIES AND WAGES	51,769	0.4	51,769	0.4	51,769	0.4	51,769	0.4	51,769	0.4
FRINGE BENEFITS	34,495		34,495		34,495		34,495		34,495	
TRAVEL										
MATERIALS AND SUPPLIES										
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
RESEARCH										
GOV'T HOLD BACK										
TOTAL	86,264	0.4	86,264	0.4	86,264	0.4	86,264	0.4	86,264	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 2012-2013		Proposed FY 2 FY 2013-2014		Proposed FY 3 FY 2014-2015		Proposed FY 4 FY 2015-2016		Proposed FY 5 FY 2016-2017	
	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE
SALARIES AND WAGES[(a)]	102,990	0.5	102,990	0.5	102,990	0.5	102,990	0.5	102,990	0.5
FRINGE BENEFITS	29,867		29,867		29,867		29,867		29,867	
TRAVEL										
RESEARH MATERIALS AND SUPPLIES	38,985[(b)]		38,985[(b)]		38,985[(b)]		38,985[(b)]		38,985[(b)]	
PUBLICATIONS										
CAPITAL EQUIPMENT										
OTHER DIRECT COSTS										
SUPPORT R&D[(c)]	(c)		(c)		(c)		(c)		(c)	
TOTAL	171,842	0.5	171,842	0.5	171,842	0.5	171,842	0.5	171,842	0.5

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

(b) For the years 1999 to 2011, the average **MATERIALS AND SUPPLIES** contribution from industry has increased to $38,985. **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 $100 million or more per approved drug.