WHITE PAPER

SUBJECT - ANIMAL HEALTH AND HUMAN FOOD SAFETY
FROM – MINOR USE ANIMAL DRUG PROGRAM
APRIL 20, 2012

EXECUTIVE SUMMARY

STATEMENT OF THE PROBLEM

Animal health and well-being is the foundation of a safe, secure and abundant food-supply. During the past century, reductions in animal diseases due to improved therapeutics and vaccines have resulted in a safer, more uniform and more economical food supply. Globalization of food markets, however, has allowed countries with less stringent animal drug approval requirements to dominate our honey, farmed shrimp and fish, venison, sheep and game bird production industries. For example, two-thirds of the honey consumed in the United States (US) is imported. Half of that honey comes from China and random samples of a small fraction of that honey were found to be tainted with banned antibiotics. Nearly 90 percent of the commercially farmed shrimp are imported; and while the US is only able to screen less than one percent, residues of banned antibiotics such as chloramphenicol have been repeatedly found. One-third of the lamb and 82% of venison consumed in the US comes from Australia and New Zealand, some of it raised with the aid of products unavailable to US producers. Clearly efforts must be initiated to provide US animal producers with safe and effective means to compete in a global market, while assuring US consumers a safe and wholesome food supply.

The process of generating the safety and efficacy data necessary for US Food and Drug Administration Center for Veterinary Medicine (FDA/CVM) approval of a drug is costly and time-consuming. At present, the estimated cost to a pharmaceutical company for research necessary to obtain FDA/CVM approval for a new drug exceeds $40 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $10 million to $25 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 the major species including cattle, swine, chickens and turkeys. There is little economic incentive for pharmaceutical firms to generate data necessary to seek FDA/CVM approval of drugs in the other so-called minor or specialty species; hence, very few drugs are available for management of diseases in these species.

Vaccines are readily available in the European Union for many of the sheep and goat diseases that cause economic hardship for US producers, Additionally, there is considerable variability in safety and sustained efficacy among veterinary vaccines in the US for both major and minor species. Standardization of vaccines and vaccinal strains as well as detailed knowledge of their safety, efficacy, and potency and of the duration of immunity are urgently needed. Inequities in drug and vaccine availability represent serious management and economic problems for producers for minor species.

ECONOMIC IMPACT OF MINOR ANIMAL SPECIES IN US IS GREAT BUT AT RISK

United States gross annual farm gate income from production of minor animal species has been estimated by producer groups at over $4.8 billion. Further, these farm gate revenues produce an economic stimulus to the US Gross Domestic Product estimated at another $37 billion. While the cumulative contribution of minor species to agricultural income is great, the return to pharmaceutical companies for research on therapeutics or vaccines for this diverse category is small and generally unprofitable. Minor and specialty use needs have thus continued to accumulate, leaving the producers of these species without the approved drugs or vaccines necessary for disease prevention and control. Lack of approved drugs and vaccines for these producers is seriously threatening the growth and long-term viability of this industry.

CHALLENGES

The Minor Use Animal Drug Program (MUADP) was created in 1982 to work with the FDA/CVM, the pharmaceutical industry and producers to facilitate approval of pharmaceuticals and provide information for the safe and efficacious use of these materials in specialty animal species. MUADP currently has 16 active projects and lists 41 pharmaceutical compounds that have been requested by producers of specialty animal species as urgently needed. Over the years, the cost for MUADP to provide information to support a single label claim has risen to approximately $3.5 million. This is almost six times the highest annual funding ever received in the 30-year history of the program.

Grant support for MUADP has never been adequate to meet the needs of specialty animal producers in the US. As a result US producers of such products are far behind their counterparts in other countries.

This lack of funding for MUADP impacts:

1. Food safety – due to the relatively unregulated importation of specialty agricultural products.
2. Food security - inability of US producers to prevent production losses with approved therapeutics forces producers to try unapproved or unregulated substances.
3. Agricultural diversity - US producers of specialty animal products cannot compete economically with foreign producers.
4. Prevention and control of zoonotic diseases – lack of approved vaccines and pharmaceuticals.
5. Animal welfare - US producers are unable to prevent and control parasitic and other diseases that inflict animal suffering.
6. Small farm economy – Concentrated animal feeding operations and vertical integration of the cattle, swine, dairy and poultry industries have forced the small family farmer to choose niche, specialty minor species markets or bankruptcy.

SOLUTION

MUADP is proposing changes to its structure, mission and funding to better serve its stakeholders. The proposed changes are designed to stimulate increased stakeholder participation and alter the program to one that takes a more hypothesis-driven, applied approach to its mission. Proposed changes will broaden the scope of MUADP and increase the ability of this program to:

1. Protect human food safety and security,
2. Increase the diversity of our agricultural base to include important specialty species,
3. Help prevent and control zoonotic diseases, and
4. Ensure the health and welfare of agriculturally important specialty animal species in the US.

FUNDING AND PROPOSED BUDGET

The amount requested for increasing MUADP activities as described is $1.9 million per year. With this funding, it is anticipated that MUADP could perform the outlined work necessary to stimulate the US niche animal markets while maintaining animal health and ensuring a safe, healthful food supply for US consumers.

TABLE OF CONTENTS

A. STATEMENT OF THE PROBLEM

1. HUMAN FOOD SAFETY

Other countries with less stringent approval requirements have a variety of production aids available that producers in the US do not have. Foreign producers of lamb, wool, cheeses, farmed fish, farmed shrimp, honey, and game-birds frequently export those products to the US and it is usually up to the importers to check for tainted foods. For example, two-thirds of the honey consumed in the US is imported. Half of that honey comes from China. A recent publication revealed that a percentage of that honey is tainted with banned antibiotics and merely returned to the seller.[1] Nearly 90 percent of the commercially farmed shrimp are imported; and while the US is only able to screen less than one percent, residues of banned antibiotics such as chloramphenicol have been repeatedly found.[2] One-third of the lamb consumed in the US comes from Australia and New Zealand, some of it raised with the aid of products unavailable to US producers.[3] Clearly efforts must be initiated to provide US animal producers with safe and effective means to compete in a global market, while assuring US consumers a safe and wholesome food supply.

2. ANIMAL DRUGS FOR MINOR SPECIES AND MINOR USES

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 US 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[1] and for the principal 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 treatment and prevention 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 as well as safe and efficacious in the target animal.

The process of generating the safety and efficacy data necessary for FDA approval of a drug is costly and time-consuming. At present, the estimated cost to a pharmaceutical company for research necessary to obtain FDA approval for a new drug exceeds $40 million, and requires 8 to 10 years of concentrated research effort. The addition of a new label claim is also costly, ranging from $10 to $25 million[4]. 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 of minor species[5-7].

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

[1] "Minor or specialty species" are defined by exclusion as animals other than dogs, cats, horses, cattle, swine, chicken, and turkeys. Included are sheep, deer, rabbits, and aquatic animals. Minor and specialty are used synonymously in this document.

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. Funding for the Minor Use Animal Drug portion of IR-4 was provided solely by a Special Research Grant (separate from the pesticide program) that was administered by CSREES; the program did not receive off-the-top funding. During this time the animal portion 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/CSREES 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, MUADP was thus created as the Minor Use Animal Drug Program. It was decided to use the newly created NRSP structure to facilitate programmatic input and administrative oversight and to help increase visibility and support for the program by involving the State Agricultural Experiment Stations and Colleges of Veterinary Medicine in the regions. There continues to be interest in using the NRSP structure to administer the program and involve SAES and the Colleges of Veterinary Medicine.

Before MUADP, private sponsors had supported approvals for the use of minor use drugs as follows: none for rabbits, one for ducks and pheasants (none for other game birds), two for food fish, four for goats and twenty-one for sheep. Since the first drug approval in 1984 under the former IR-4 program, NRSP-7 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 (Table 1). 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. 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 16 active research projects involving nine animal species and 12 different drugs. Further, the number of highest priority projects has been estimated at approximately 41. Added to our 16 current active projects, the backlog of projects represents a research commitment stretching over several decades or a shorter-term commitment at a much higher level of funding than is presently allocated to the MUADP[5, 7, 8].

3. VETERINARY VACCINES

During the past century, reductions in animal diseases due to improved therapeutics and vaccines have resulted in a safer, more uniform and more economical food supply. At this time, however, there is considerable variability in safety and sustained efficacy among veterinary vaccines. Standardization of vaccines and vaccinal strains and detailed knowledge of their safety, efficacy, and potency and of the duration of immunity are urgently needed.[9, 10] For example, vaccines are readily available in the European Union for many of the sheep and goat diseases that cause economic hardship for US producers, Numerous examples of these shortages exist. US-approved vaccines are needed against *Toxoplasma* gondii and *Chlamydophila abortus* for abortion diseases in sheep and goats; *Mannheimia haemolytica*

vaccine against respiratory disease in sheep and goats; VHD vaccine against viral haemorrhagic disease in rabbits, and many vaccines for bird infectious diseases.[11]

Table 1. Minor Use Animal Drug Program Drug Approvals and Activity by Industry.

	ACTIVITY	
INDUSTRY	APPROVALS	ACTIVE PROJECTS
Game Bird	**Chukar partridges** Sulfadimethoxine/Ormetoprim Lasalocid **Pheasants** Amprolium Thiabendazole **Quail** Salinomycin Bacitracin Monensin	**Pheasants** Lasalocid Fenbendazole
Rabbits	Lasalocid	Ivermectin
Honey Bees	Tylosin Lincomycin	
Cervid	**Bison** Ivermectin **Reindeer** Ivermectin	**Deer** Lasalocid **Fallow Deer** Fenbendazole
Meat Goats	Fenbendazole Monensin Decoquinate Morantel tartrate	Lasalocid CIDR (progesterone) Tulathromycin
Dairy Goats	Fenbendazole Monensin Decoquinate Morantel tartrate	Lasalocid CIDR (progesterone) Ceftiofur HCl (Intramammary) Tulathromycin
Sheep	**Bighorn Sheep** Fenbendazole **Sheep** Decoquinate Ceftiofur Tilmicosin phosphate CIDR (progesterone)	**Sheep** Tulathromycin Florfenicol
Catfish/Aquaculture†	**Catfish** Sulfadimethoxine/Ormetoprim Florfenicol **Finfish** Formalin Oxytetracycline Hydrogen peroxide Florfenicol **Lobster** Oxytetracycline	**Fish** Sulfadimethoxine/Ormetoprim Erythromycin Carp pituitary Oxytetracycline Strontium chloride Ionophores Florfenicol **Shrimp** Florfenicol

†Approvals resulted in an additional 16 label claims for these aquatic species.

B. Economic Impact of Minor Animal Species

United States gross annual farm gate income from production of minor animal species has been estimated by producer groups at over $4.8 billion. Further, these farm gate revenues produce an economic stimulus to the US gross domestic product estimated at another $37 billion (Table 2). While the cumulative contribution of minor species to agricultural income is great, the return to pharmaceutical companies for research on therapeutics or vaccines for this diverse category is small and generally unprofitable. Minor and specialty use needs have thus continued to accumulate, leaving the producers of these species without the approved drugs or vaccines necessary for disease prevention and control.

Table 2. US Farm Gate Value and Economic Impact of Minor Species by Industry and Leading States

Industry	Leading States	US Farm Gate Value [$M]	US Economic Impact [$M]
Game Bird	TX, NC, PA, KS, WI, NY, IL, SD, FL, MN, IA, GA, MS, IN & AL.	$897	$5,401
Rabbits	CA, GA, OH, PA, & TX	$21.6	$898
Honey Bees	ND, CA, SD, FL, MT, MN, TX, & WI.	$166	$17,284
Cervid	TX, PA, OH, FL, LA, IA, & KS	$966 (farming) $817 (hunting)	$3,241
Meat Goats	TX, TN, CA, GA, OK, NC, KY, MO, FL, & AL	$187 $205 (breeding)	$1,123
Dairy Goats	TX, OH, NY, PA, WI, WA, IN, CA, MD, MN, MI, FL, & KS.	$63.0 $16.0 (export)	$474
Sheep	TX, CA, WY & CO	$810	$4,861
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
	Total =	**$4,761**	**$36,564**

C. Challenges

As previously described, the Minor Use Animal Drug Program was created in 1982 to work with the FDA/CVM, the pharmaceutical industry and producers to facilitate approval of pharmaceuticals and provide information for the safe and efficacious use of these materials in specialty animal species. The Minor Use Animal Drug Program currently has 16 active projects and lists 41 pharmaceutical compounds that have been requested by producers of specialty animal species as urgently needed. The costs for the Minor Use Animal Drug Program to provide information to support a single label claim have risen to approximately $3.5 million. This is almost six times the highest annual funding ever received in the 30-year history of the program.

The funding for the Minor Use Animal Drug Program has never been adequate to meet the needs of specialty animal producers in the US. As a result US producers of such products are far behind their counterparts in other countries. This lack of funding for the Minor Use Animal Drug Program impacts:

1. Food safety –imports of specialty agricultural products are relatively unregulated.
2. Food security - US producers are unable to prevent production losses.

3. Agricultural diversity - US producers of specialty animal products cannot compete economically with foreign producers.

4. Prevention and control of zoonotic diseases – Approved vaccines and pharmaceuticals are lacking.

5. Animal welfare - US producers are unable to prevent and control parasitic and other diseases that inflict animal suffering.

6. Small farm economy – Concentrated animal feeding operations and vertical integration of the cattle, swine, dairy and poultry industries have forced the small family farmer to choose niche opportunities with specialty or minor species markets or face bankruptcy.

D. SOLUTIONS

1. MINOR USE ANIMAL DRUG PROGRAM MISSION, VISION AND OBJECTIVES

(A) MISSION. The mission of the Minor Use Animal Drug Program is to enhance human food safety, food security, agricultural diversity, and animal well being through the development of orphan veterinary therapeutics and immunizing agents for agriculturally important specialty animal species.

(B) VISION. The Minor Use Animal Drug Program is proposing changes to its structure, mission and funding to better serve its stakeholders. The proposed changes are designed to stimulate increased stakeholder participation and alter the program to one that takes a more hypothesis-driven, applied approach to its mission.

Proposed changes will broaden the scope of the Minor Use Animal Drug Program and increase the ability of this program to:

1. Enhance human food safety and security,
2. Increase the diversity of our agricultural base to include important specialty species,
3. Help prevent and control zoonotic diseases, and
4. Ensure the health and welfare of agriculturally important specialty animal species in the US.

(C) OBJECTIVES. The major objectives of the program are:

1. To support hypothesis-based and applied research central to human food safety and the health and well-being of agriculturally important specialty animal species.
2. To establish a national program that has sufficient logistical and analytical support, quality assurance and any other assistance required for the generation of data to facilitate the licensing and approval of pharmaceuticals, anthelmintics, vaccines, and reproductive aids for agriculturally important, specialty animal species.

E. TECHNICAL SPECIFICATIONS

1. PROPOSED FUNDING MECHANISMS AND PROGRAM SUSTAINABILITY STRATEGIES

(A) FUNDING. It is proposed that the Minor Use Drug Program remain as a budgetary line item and structured as a competitive grant program with annual Requests for Proposals (RFPs) from USDA/CSREES emphasizing the importance of this program to specialty animal agriculture. This will help ensure that the program will not be lost within the USDA budget. Technically this entails creating a hybrid funding structure of the funding authority from Section 2(c)(1)(B) of the Competitive, Special, and Facilities Research Grant Act of August 4, 1965, Public Law No. 89-106, as amended by combining aspects of (7 USC 450i (c)(1)(B)) and 7 U.S.C. 450i(b) (National Agricultural Research, Extension and Teaching Policy Act of 1977). That is to say, the program should be a combination of the Special grants program (c) and the Competitive grants program (b) in 7 U.S.C 450i.

(B) INDEPENDENT STAKEHOLDER ADVISORY GROUP. An independent stakeholder advisory group will be established with a chairperson and a set of officers. This group will advise Minor Use Animal Drug Program on setting research priorities. It will promote the program to the US Secretary of Agriculture and appropriate governmental agencies. The stakeholders will provide support as needed to help assure sustained and appropriate funding.

2. FUNDING AGENCY SUPPORT OF PROGRAM MISSION AND ADMINISTRATION

(A) GRANT PREPARATION AND REVIEW. USDA/CSREES or its descendant will oversee preparation and review of grant proposals for both the National Headquarters and Regional Laboratories.

(B) PROGRAM REVIEW. Grants submitted to the funding agency in response to RFPs will undergo a peer-review process coordinated by the National Headquarters and appropriate regional coordinators. Additionally, Minor Use Animal Drug Program will be subject to program review every five years by the Funding Agency(s).

(C) FUNDING DISTRIBUTION. USDA/CSREES or its descendant will control and coordinate distribution of grant funding to the National Headquarters and Regional Laboratories. The National Headquarters and appropriate regional coordinators will coordinate review of grant proposals from associate laboratories. Depending on the nature of the research proposal, funding for associate laboratory research projects may be contingent on protocol concurrence from the Office of New Animal Drug Evaluation (FDA/CVM) or other appropriate regulatory body.

3. MINOR USE ANIMAL DRUG PROGRAM STRUCTURE AND COORDINATION OF ACTIVITIES

The following changes are designed to make Minor Use Animal Drug Program more fluid and better able to respond to the needs of specialty animal producers. It will increase the cooperation among CSREES, Central, regional and associate laboratories, industry, and stakeholders. These changes will facilitate the design and conduct of research studies and encourage a more rapid development and presentation of data to the scientific community.

(A) COMPETITIVE PROGRAM. It is proposed that a competitive grant program be added to Minor Use Animal Drug Program. Competition for funding and participation in the program will be open to any eligible institution in the US. It is recognized that a significant increase in funding over time will be required to meet expanded program objectives.

(B) NATIONAL HEADQUARTERS. To enhance the program mission, it is proposed that Minor Use Animal Drug Program establish a National Headquarters to coordinate and facilitate research and funding as well as interact more directly with stakeholder groups. The National Headquarters will prepare research study protocols, coordinate with appropriate regulatory bodies, provide quality assurance and write and submit study reports. The National Headquarters will establish subcontracts with participating investigators and institutions. The National Headquarters will sponsor an annual meeting for the exchange of information that will serve as a conduit for presentation of original research.

(C) REGIONAL LABORATORIES AND COORDINATORS. Minor Use Animal Drug Program will staff regional laboratories at Colleges of Veterinary Medicine in each of four regions (Northeast, North Central, Southern and Western). The regional laboratories will conduct original research at their own institutions and facilitate the conduct of original research in associate laboratories throughout the US. The regional laboratories will employ and train personnel to conduct research studies. The regional laboratories will also work with commercial firms involved in development of pharmaceuticals and vaccines. The regional laboratories will provide analytical support for quantifying drug residues in tissues and on-site quality assurance/quality control

where needed to ensure the proper conduct of all studies. The regional laboratories will assist in writing study reports as needed.

(D) ASSOCIATE LABORATORIES. Funding will be open to any research facility in the US to take advantage of unique expertise, facilities and equipment. These laboratories will coordinate their activities with the National Headquarters and regional laboratories to ensure conduct of studies that meet GLP or GCP standards and the needs of regulatory bodies such as the FDA/CVM.

4. STAKEHOLDER SUPPORT LEVEL AND MECHANISMS

(A) PHARMACEUTICAL INDUSTRY SUPPORT. The pharmaceutical industry has been generous in their support for Minor Use Animal Drug Program. Without their contributions, the program could not function at all. Estimates from industry representatives indicate that it currently requires $10 million to $25 million to obtain a label claim on a veterinary pharmaceutical for a major animal species. Once the label claim has been approved, Minor Use Animal Drug Program can utilize information from the required studies. The value of industry contributions for a single approval range from $4 to $8 million for each pharmaceutical. Contributions from industry are expected to continue and have included:

1. Study protocols for product approval used for major agricultural species.
2. Toxicology Packages that can be utilized directly for approval.
3. Environmental Impact Statements that can be modified to support approval of a product for a specialty animal species.
4. Analytical methods and technical assistance on development and validation of methods for specialty animal species.
5. Provision of analytical-grade pharmaceuticals as standards for analysis
6. Provision of analysis - some firms have provided residue analysis for Minor Use Animal Drug Program.
7. Provision of pharmaceuticals, vaccines, reproductive aids, etc., at no cost to Minor Use Animal Drug Program.

(B) PRODUCER SUPPORT. Minor Use Animal Drug Program enjoys considerable producer support despite the fact that it has been chronically underfunded. Producers have provided lobbying support as well as financial support for this program. Financial support varies with the needs of particular studies and can range to over $100,000. Expenses for test animals and per diem charges have escalated in recent years. Contributions take the form of:

1. Animals provided by producers,
2. Facilities for studies provided by producers (especially important for some efficacy studies).
3. Lobbying support.

(C) UNIVERSITY SUPPORT. Universities have provided laboratory and analytical facilities and such contributions are expected to continue.

(C) FDA/CVM SUPPORT. Minor Use Animal Drug Program currently maintains an excellent relationship with the Center for Veterinary Medicine (FDA/CVM). Over the past 24 years, CVM has:

1. Provided a full-time liaison to the Minor Use Animal Drug Program.
2. Provided guidance in development of approved protocols by the Office of New Animal Drug Evaluation (ONADE).
3. Minor Use Minor Species (MUMS) Act: Private industry funded under the Minor-Use Minor Species Act through the FDA will be able to cooperate with and receive assistance from Minor Use Animal Drug Program.

As this relationship has proven beneficial to CVM reviewers, the Minor Use Animal Drug Program, stakeholders and veterinary pharmaceutical companies, all parties expect this support to continue.

F. FUNDING

US DEPARTMENT OF AGRICULTURE/COOPERATIVE STATE RESEARCH EDUCATION AND EXTENSION SERVICES (USDA/CSREES) has been the direct source of funding for the Minor Use Animal Drug Program as a line item in the USDA budget for 26 of its 30 years. In 2007, 2008, 2011 and 2012 funding was provided through Hatch Funds administered by the Experiment Stations Directors. This funding provided less than 50% of the Minor Use Animal Drug Program operating budget (Table 3) for those four years. USDA/CSREES also provides a full-time liaison to the Minor Use Animal Drug Program.

Table 3. Federal and Nonfederal Minor Use Animal Drug Program Funding Over the Last Seven Years
(in thousands of dollars)

	Source of Funding				
Year	USDA	FDA/CVM	State	Industrial	% USDA
2005	$588	$162	$69	$84	65%
2006	$588	$167	$71	$87	64%
2007†	$279	$173	$74	$90	45%
2008†	$325	$177	$75	$92	49%
2009	$429	$182	$78	$94	55%
2010	$429	$189	$80	$98	54%
2011†	$325	$191	$81	$99	47%
2012†	$325	$193	$82	$100	46%
Total	$3,288	$1,434	$611	$744	54%

†Funding provided through Hatch Funds administered by regional AES.

The amount requested for increasing the Minor Use Animal Drug Program activities as described is $1.9 million per year. A breakdown of this budget is presented in Table 4.

Table 4. Proposed Budget for First 12-Month Period (Direct Costs Only)
NATIONAL HEADQUARTERS

PERSONNEL

Role on Project	% Effort	Salary Requested	Fringe Benefits	Totals
Program Director	50	65,000	21,450	86,450
Program Assistant	100	56,000	18,480	74,480
Quality Assurance	100	56,000	18,480	74,480
MATERIALS AND SUPPLIES				
Postage, office supplies, software, phone, fax, storage files and commercial printing work				15,000
TRAVEL				
Six to eight major fixed trips per year for study review. Five trips to Washington, DC area.				10,000
TOTAL				260,410

EACH OF FOUR REGIONAL LABORATORIES

PERSONNEL

Role on Project	% Effort	Salary Requested	Fringe Benefits	Totals
Regional Coordinator	20	30,000	9,900	39,900
Analytical Chemist or Immunologist	100	73,000	24,090	97,090
Research Associate	100	52,000	17,160	69,160
Graduate Assistant	100	33,000	10,890	43,890
Hourly Labor	As needed	10,000	2,500	12,500
MATERIALS AND SUPPLIES†				
Materials and supplies include laboratory chemicals, agar, histology supplies and chemicals, therapeutic compounds, maintenance supplies for laboratory equipment maintenance contracts, shipping samples, solid phase extraction columns, general lab supplies, HPLC columns and supplies, waste disposal, gases, publication costs and other miscellaneous supplies.				100,000
ANIMALS AND PER DIEM††				
Animals and animal feed to complete target animal safety, efficacy and residue depletion studies necessary for providing essential data for FDA/CVM approval.				30,000
TRAVEL				
Two trips per year for the regional coordinator and one trip per year for the three professionals to present at scientific meetings.				10,000
TOTAL FOR EACH OF THE FOUR REGIONAL LABORATORIES				400,040
PROGRAM DIRECT COSTS				2,203,070
INDIRECT COST TOTAL @ 20%				440,614
PROGRAM TOTAL				1,860,570

†Regional budgets may differ in this section as regional labs contribute differing expertise to the program.

†† Specific budgets will be developed in accordance with the administrative structure described in this document for the operation of the MUADP, which includes a vote of the Technical Committee for the approval of any project undertaken.

G. SUMMARY

Globalization of food markets has allowed countries with less stringent animal drug approval requirements to dominate our farmed fish, shrimp, honey and game bird production industries. Efforts must be initiated to provide US animal producers with safe and effective means to compete in a global market, while assuring US consumers a safe and wholesome food supply. The process of generating the safety and efficacy data necessary for US Food and Drug Administration Center for Veterinary Medicine (FDA/CVM) approval of a drug, however, is costly and time-consuming. There is little economic incentive for pharmaceutical firms to generate data necessary to seek FDA/CVM approval of drugs for minor or specialty species.

Vaccines are readily available in the European Union for many of the sheep and goat diseases that cause economic hardship for US producers. Additionally, there is considerable variability in safety and sustained efficacy among veterinary vaccines in the US for both major and minor species. Inequities in drug and vaccine availability represent serious management and economic problems for producers of specialty species.

United States gross annual farm gate income from production of minor animal species has been estimated by producer groups at over $4.8 billion. Further, these farm gate revenues produce an economic stimulus to the US gross domestic product estimated at another $37 billion. Lack of approved drugs and vaccines for these producers is seriously threatening the growth and long-term viability of this industry.

The Minor Use Animal Drug Program was created in 1982 to work with the FDA Center for Veterinary Medicine, the pharmaceutical industry and producers to facilitate approval of pharmaceuticals and provide information for the safe and efficacious use of these materials in specialty animal species. The Minor Use Animal Drug Program currently has 16 active projects and lists 41 pharmaceutical compounds that have been requested by producers of specialty animal species as urgently needed. The funding for the Minor Use Animal Drug Program has never been adequate to meet the needs of specialty animal producers in the US. As a result, US producers of such products are far behind their counterparts in other countries.

The Minor Use Animal Drug Program is proposing changes to its structure, mission and funding to better serve its stakeholders. The proposed changes are designed to stimulate increased stakeholder participation and alter the program to one that takes a more hypothesis-driven, applied approach to its mission. Proposed changes will broaden the scope of Minor Use Animal Drug Program and increase the ability of this program to:

(1) enhance human food safety and security,
(2) increase the diversity of our agricultural base to include important specialty species,
(3) help prevent and control zoonotic diseases, and
(4) ensure the health and welfare of agriculturally important specialty animal species in the US.

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