Project No. and Title: NECC2220 A National Agricultural Program for Minor Use Animal Drugs

Period Covered: 10-2023 to 09-2024

Date of Report: 11-16-2024

Annual Meeting Date: September 27, 2024

Participants

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Summary of Minutes of Annual Meeting

12:00 PM Meeting organization

Report from The Administrative Advisor - Dr. Margaret Smith

Report from The National Coordinator - Dr. John G. Babish

Report from FDA/CVM – Dr. Amy Omer

Regional Accomplishments

Northeast Region: Dr. Rodman G. Getchell

North Central Region – Drs. Ronald W. Griffith and Amanda Kreuder

Other business

Conclusion

Report from The Administrative Advisor - Dr. Margaret Smith

Dr. Smith opened the meeting describing the purpose of this meeting to fulfill the Program’s obligation to submit an annual report. She then thanked all members for their hard work and dedication over the past year.

Report from The National Coordinator - Dr. John G. Babish

* 1. Tactical Science Network (TSN) wrap-up

There has been little progress regarding the consolidation of the TSN into a formal budget proposal. No format meetings of the TSN were held during the 2003-2004 period. We are awaiting a final report.

1. Follow-up with stakeholders for support in House Farm Bill

Dr. Babish (JGB) held discussions with Tyler Gutchess. Legislative Assistant to U.S. Representative Marc Molinaro (NY-19). During these discussions, he presented background information and funding needs of the Program during the period of 8/27/23 to 10/ 10/4/23. In addition to providing written background information on the Program’s accomplishments and needs, a thirty-minute phone call was held on 10/4/23 to more clearly define the Program’s condition.

1. Congressional progress on Farm Bill

A version of the Farm Bill has been passed by the United States Senate and a draft Farm Bill left the United States House Agriculture Committee in the late spring of 2024. The draft Farm Bill remans in House and is currently held back due to general budget issues and a newly passed continuing resolution.

1. Other funding pursuits

Notice of a Funding Opportunity titled Animal and Veterinary Innovation Centers (AVIC) was published late this year. As the U.S. Food and Drug Administration’s Center for Veterinary Medicine continues to progress in the implementation of its Animal and Veterinary Innovation Agenda, the center is supporting a collaborative agreement to the Reagan-Udall Foundation for the FDA (the Foundation) to conduct a strengths, weaknesses, opportunities, and threats (SWOT) analysis. This SWOT analysis aims to research the challenges within, and unmet needs of, the animal health, animal food and veterinary industries, and explain the economic impact of these gaps. The Program plans to file a proposal during the next cycle of funding this spring.

1. Contact with stakeholders

A Twitter Account (X) was established to correspond directly with stakeholders. The following stakeholder groups were identified in Twitter:

@Agencies – Fish and Wildlife Service, and Animal and Plant Health Inspection Service, US Geologic Survey, and FDA Center for Veterinary Medicine. @Aquaculture: Marine Fish Dealers, American Tilapia Association, U.S. Trout Farmers Association, American Fisheries Society, World Aquaculture Society, Aquaculture Network Information Center, and Catfish Planet. @Bees: American Beekeepers Federation, American Honey Producers Association, International Bee Research Association, Iowa State Entomology Index: Beekeeping, and Beekeeper’s Home Pages Internet Resources. @Game Birds: Mississippi State Game Bird Management, Pheasants Forever, Quail World, and North American Game Bird Association @Caprine: AmericanDairyGoatAssociation. @Lagomorphs: American Rabbit Breeders Association. @Ovine: AmericanSheepIndustryAssociation, @Ratites: American Emu Association and The American Ostrich Association @Reptiles: The Gator Hole and Crocodilian Internet Resources @Ungulates: Alpaca Registry, National Bison Association, The White-Tailed Deer Farmer’s Network, North American Deer Farmers Association, Deer Hunting Net, and North American Elk Breeders Association. @Farm Bill Facts, and @U.S. Farmers & Ranchers in Action

The keywords used for directing Program posts included: #sheep, #Goats, #MeatGoats, #DairyGoats, #Gamebirds, #Pheasants. #Quail, #ChukarPrtridges, #Rabbits, #Foxes, #HoneyBees, #Bison, #Reindeer, #Catfish, #Finfish, #Lobster, #Shrimp. #Emu. #Llama, #Alpaca, and #Vicuna. These keywords assist in directing Program posts to potential stakeholders, and increase followers and supporters.

Report from Center for Veterinary Medicine – Dr. Amy Omer

Drug Approval Work:

1. Fenbendazole in quail:

Overview: MUADP continued the collaboration with their research partners, Merck Animal Health, and Dr. Ron Kendall of Texas Tech University, to generate the data necessary to obtain FDA approval of fenbendazole-medicated feed for the treatment of nematodes in quail. This project has impact for both wild quail and farmed quail.

New Approval: Data generated through MUADP research collaborations resulted in the completion of the Effectiveness, Target Animal Safety, and Human Food Safety technical sections for the use of fenbendazole in quail. With these technical sections completed, Merck Animal Health was able to utilize these data to support a New Animal Drug Application. On May 23, 2024, the FDA issued a supplemental approval for Safe-Guard (fenbendazole) for the treatment and control of gastrointestinal worms (*Aulonocephalus* spp.) in wild quail (NADA 131-675). Prior to this approval, no anthelmintics were approved for use in quail; successful completion of this project has provided access to a class of therapeutic drugs previously unavailable for quail.

Future approval: MUADP intends to leverage the data generated for the approval described above to support another supplemental approval of fenbendazole for use in farmed quail. On August 13, 2024, MUADP requested a Target Animal Safety technical section complete letter for the designated indication: “For the treatment and control of adult *Heterakis gallinae* and *Capillaria* spp. in quail”; CVM has six months to review this request. Because the duration of dosing for this indication is less than that already proven to be safe, no additional target animal safety data will need to be generated. Similarly, the previously conducted residue depletion work for fenbendazole in quail will be cited to support the Human Food Safety technical section for this indication in farmed quail.

1. Tulathromycin for respiratory disease in goats:

Overview: Bacterial pneumonia is a major cause of morbidity and mortality in goats and represents a significant welfare challenge for operations in the US. In contrast to major food producing species such as cattle and swine, there is currently only a single antibiotic (ceftiofur) labeled for treatment of respiratory disease in goats. Therefore, there is a substantial need for additional FDA-approved labelled products for treatment of respiratory disease in goats. This project will address this unmet need and generate data necessary for the approval of tulathromycin in goats for treatment of respiratory disease.

Effectiveness: Dr. Amanda Kreuder of Iowa State University College of Veterinary Medicine conducted two independent effectiveness studies of tulathromycin in goats during the Summers of 2022 and 2023. These data sets are currently being prepared for submission to FDA-CVM.

Human Food Safety: To address the Human Food Safety technical section, a residue depletion study must be conducted in order to establish an appropriate withdrawal period for tulathromycin in goats, but prior to conducting the required residue depletion study, the analytical method for the determination of the marker residue in samples generated from the residue depletion study must be validated.

Dr. Pat Gorden of Iowa State University College of Veterinary Medicine received concurrence from FDA-CVM on a method validation study protocol to validate an analytical method for the detection and quantification of tulathromycin in caprine liver. He then applied and was awarded a Minor Use Minor Species (MUMS) grant to fund the method validation study.

In January of 2024, Dr. Gorden also received concurrence from FDA-CVM on a residue depletion study protocol. In September of 2024, he was awarded a second MUMS grant to fund the study.

Regional Accomplishments

Northeast Region: Dr. Rodman G. Getchell

This year I was not able to attend the AADAP stakeholder meeting in Bozeman, MT due to health reasons. My final study report on the safety of A*QUAFLOR®* in medicated feed provided to marine fish species (*The Safety of AQUAFLOR (50% florfenicol) Administered in Feed to a Marine Finfish Species, Red Drum*) was submitted to ONADE for review. My previous Clownfish Target Animal Safety study with AQUI-S 20E*®* was accepted by FDA, which was good news.

Further MUMS-sponsored projects were delayed in 2024 due to Merck failing to meet with FDA CVM to have their required PSC before the July deadline for proposals.  We plan to try for the late fall submission instead, so we should have an answer by then about whether a second florfenicol study, possibly with Atlantic salmon, is necessary.

The other related meetings, besides our monthly MUADP meeting, which I also participate in, include the thrice-yearly conference calls with the Aquatic Drug Approval Coalition (ADAC) where state, federal, academia and aquaculture industry representatives meet with FDA CVM staff to provide avenues to streamline the aquatic drug approval process. As one of the most effective stakeholders in the drug approval process, the ADAC shares many of the goals of the MUADP, particularly those veterinarians providing services to clients culturing aquatic animals and conducting fisheries management activities. ADAC’s purpose is to develop and maintain a concerted voice bringing together representatives from the various factions of the aquatic drug approval arena: state and federal partners, fisheries organizations, drug sponsors, and the private aquaculture industry. Both groups work on common problems with drug approval requirements needed by the aquaculture industry and the fish vets that provide care for these animals. Ultimately both groups want to promote the development and use of safe and effective drugs.

The Drug Approval Working Group and ADAC Meeting occurred on Sunday, February 18th, 2024, before the Aquaculture America 2024 Meeting in San Antonio, TX. I was not able to attend but can provide a short summary of topics addressed. Updates/Reports from Partners: USFWS (D. Miko), DAWG (Alan Jackson), FDA-CVM, AADAP (Guppy Blair), and NOAA (J. Whaley) was on the agenda. The rest of the meeting included presentations on the next Unmet Drug Needs Survey and the ADAC 5-year Plan. I did attend the virtual ADAC-FDA triannual conference calls, including one on December 7th, 2023, and the other that occurred on March 14th, 2024.

North Central – Drs. Ronald W. Griffith and Amanda Kreuder

Last year Dr. Amanda Kreuder of Iowa State University College of Veterinary Medicine received concurrence from FDA-CVM on a field study protocol to demonstrate effectiveness of tulathromycin injectable solution, indicated for the treatment of respiratory disease in goats associated with *Mannheimia haemolytica*, *Bibersteinia trehalosi*, and *Pasteurella* *multocida*. A protocol for the residue depletion study is being developed in order to establish an appropriate withdrawal period for tulathromycin in goats. This residue study will be contracted to a Good Laboratory Practices certified lab under the oversite of Ms. Cat Bens.

Other Business

No further business was brought forward,

Conclusion

This report encapsulates recent activities and developments of the MUADP concerning the TSN grant conclusion, congressional progress on the Farm Bill, and funding opportunities through collaborative engagement and stakeholder communication. Continued efforts are essential to promote the program and facilitate the necessary legislative support. The meeting was adjourned at 1:25 pm.

Respectfully submitted,