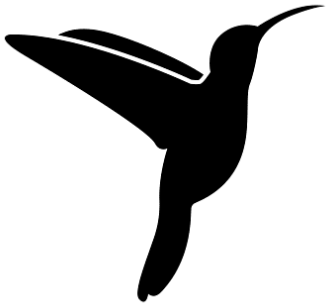
Office of Minor Use & Minor Species Animal Drug Development (OMUMS)
FDA Center for Veterinary Medicine (CVM)

Spring/Summer 2023 Newsletter



This newsletter serves to keep our stakeholders aware of the work ongoing in OMUMS. Our Office manages several programs to encourage the legal availability of new animal drugs for minor uses in the seven major species (horses, cows, pigs, chickens, turkeys, dogs, and cats) and for use in minor species (all the rest).

News

Welcome Back, Dr. Anna Nevius!

We are incredibly lucky to have Dr. Anna Nevius back with us as a rehired annuitant until December 31, 2023. She will be working with our Office on a variety of statistical projects within the Minor Use Animal Drug Program. Welcome back, Anna!

Detailees

Thank You, Dr. Olgica Ceric!

Dr. Olgica Ceric recently completed a 90-day detail in the Office of Minor Use and Minor Species. During her time in OMUMS, she provided her expertise and much needed assistance for each of our programs. She leveraged her contacts within the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) community to help identify experts in gamebird management at participating universities. These efforts will aid the Minor Use Animal Drug Program in better understanding gamebird management practices to support future drug approvals. Dr. Ceric also completed reviews for both the Indexing and Designation programs and assisted with a minor use assessment. OMUMS is very grateful to Dr. Ceric for her help during our period of transition.

Welcome, Dr. Stacey Shults!
In July, Dr. Stacey Shults will join OMUMS for a 90-day detail. Stacey has been working in CVM's Office of Surveillance and Compliance since 2008, where she serves as a senior regulatory review scientist. Stacey has provided input on various OMUMS projects over the years and participated in the working group that wrote Guidance for Industry (GFI)#261: Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs. Prior to CVM, she was a full-time small animal (and occasional pocket pet!) veterinarian in a busy practice for over 15 years. She earned her Bachelor of Science degree from James Madison University and her Doctor of Veterinary Medicine from the Virginia-Maryland Regional College of Veterinary Medicine.

Dr. Meg Oeller receives FDA Distinguished Career Service Award
In recognition of her dedication, contributions, and achievements in the area of drug availability for minor species and minor uses, Dr. Meg Oeller is the recipient of the FDA Distinguished Career Service Award. This award honors those employees whose distinguished career service merits special recognition on their retirement with a letter from the Commissioner and an inscribed clock.

During her distinguished 30-year career at FDA, Dr. Meg Oeller exhibited passion and leadership in the area of drug availability. Dr. Oeller began her career at FDA as a Veterinary Medical Officer when she reviewed, among other things, aquaculture drugs. She parlayed this drug approval experience and knowledge of minor species to become FDA's Liaison to the USDA Minor Use Animal Drug Program (MUADP). With her leadership, MUADP's research resulted in the approval of several drugs critical to agricultural minor species such as sheep, finfish, and honeybees. Dr. Oeller was then instrumental in the passage of the Minor Use and Minor Species (MUMS) Animal Health Act of 2004.

As a subject matter expert, she provided technical assistance to develop the legislation and managed CVM's relationship with the MUMS Coalition, the group of minor species organizations that helped develop and lobby on behalf of the MUMS Act. Dr. Oeller then went

on to become Director of the Office of Minor Use and Minor Species Animal Drug Development (OMUMS). In this role, her strategic vision and management positively impacted animal health by ensuring increased availability of drugs for minor species and minor uses through programs such as Indexing, Designation and the MUMS grant program.

Throughout her career, Dr. Oeller worked tirelessly advocating for access to needed drugs for all animals, no matter how rare or how small the market. Her substantial contributions to human and animal health exemplify the Agency's public health mission.

Photo courtesy of Stuart Jeffrey

The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index)

The Index is intended to provide a legal marketing status for products for non-food-producing minor species, such as laboratory rodents, zoo animals, ornamental fish, pocket pets, and pet birds. It is a process that relies partly on a risk-benefit analysis from a panel of outside experts. To date, we have added 16 products to the Index and have more drugs in the pipeline. See: **MUMS Indexing webpage**.

Updates from the Indexing Program:

- We are making progress to revise and update our Guidance for Industry (GFI) #210 to reflect our current thinking. Please visit our website for more information on how we got here and our plans moving forward.
- On March 27, 2023, Dr. Lucy Lee presented an overview of the indexing program virtually to our stakeholders at the 2023 Aquaculture Drug Approval Coordination Workshop.

MUMS Designation Program

This program is similar to the Orphan Drug Program for human medicine. It provides pharmaceutical sponsors with the opportunity to apply for grants to help support safety and effectiveness testing of new animal drugs, and awards seven years of exclusive marketing rights when the drug is approved or conditionally approved.

Currently, we have 165 designations total, including 52 active designations (those still pursuing approval = not already approved, conditionally approved or terminated) on the list.

See the **Drug Designation webpage** for the complete list, including a sortable Excel version.

We completed the second of two open periods for MUMS grant applications for fiscal year 2023 in February. Links to information about MUMS grants and how to apply are available on the Drug Designation webpage. The current open period for fiscal year 2024 Part 1 grant applications runs from May 26, 2023, to July 28, 2023.

The FDA MUMS Grant Program awarded one $250,000 grant for the Fiscal Year 2023, Part 1 grant application period and one grant for $249,504 for the Fiscal Year 2023, Part 2 grant application period.

To date, the MUMS Grant Program has awarded a total of $7.07 million to fund studies that support MUMS drug approval.

Minor Use Animal Drug Program

The MUADP is a USDA program that generates scientific data to support FDA approval of new animal drugs for minor species of agricultural importance. The program works to complete four of the technical sections required for approval: effectiveness, target animal safety, human food safety, and environmental impact. Pharmaceutical sponsors can then use this information along with their own manufacturing and labeling information when they apply for drug approval.

Active MUADP Projects

Project	Effectiveness	Target Animal Safety	Human Food Safety	Environmental Impact
Progesterone CIDR for estrus synchronization in goats	Final Study Report pending	*Complete*	*Complete*	*Complete*
Fenbendazole for nematodes in pheasants	*Complete*	*Complete*	*Complete*	Categorical Exclusion request pending
Fenbendazole for nematodes in wild quail	*Complete*	*Complete*	*Complete*	To be addressed by the manufacturing sponsor
Erythromycin for Bacterial Kidney Disease in freshwater-reared salmonids	*Complete* for Chinook	*Complete*	*Complete*	Draft environmental assessment pending
Tulathromycin for respiratory disease in goats	Protocol concurred – Studies ongoing	*Complete*	Protocol under review	*Complete*

Project updates from the MUADP:

- **Fenbendazole for Quail:** The MUADP continues their research partnership with Texas Tech University's Wildlife Toxicology Laboratory to gain approval of fenbendazole Type A medicated article for the control of parasites in free-ranging quail. The program recently received a technical section complete letter for **target animal safety**. The technical section is complete for the use of fenbendazole Type A medicated article for the treatment and control of cecal worms (*Aulonocephalus* spp.) in wild quail.

- **Tulathromycin for Goats:** The MUADP, in cooperation with Iowa State University, continues their work on the project to support approval of tulathromycin for the treatment of respiratory infections in goats. In the Summer of 2023, the second of two required effectiveness studies will be

conducted. Also, to prepare for future residue depletion studies, the program has developed a protocol to validate the analytical method for tulathromycin in caprine liver.

OMUMS Celebration Luncheon

From left to right: Anna Nevius, Meg Oeller, Dorothy Bailey, Lucy Lee, A'ndrea Van Schoick, Janah Maresca, Danny Skirvin, and Amy Omer.

For further information about OMUMS and our programs, please visit our **website**.

Contact Us

Dr. Dorothy Bailey, Acting OMUMS Director

Designation/Grant questions: Dr. Stuart Jeffrey or Dr. Janah Maresca

Indexing questions: Dr. Lucy Lee or Dr. Danny Skirvin

MUADP questions Dr. Amy Omer or Dr. A'ndrea Van Schoick