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

Spring 2024 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

Congratulations to new OMUMS Director, Dr. Dorothy Bailey!

Dorothy Bailey, DVM, a 17-year veteran of the Agency, has been appointed the Director of the Office of Minor Use and Minor Species (OMUMS) in the Center for Veterinary Medicine at the U.S. Food and Drug Administration. Dr. Bailey has been the Acting Director of OMUMS since the previous director, Dr. Meg Oeller, retired at the end of 2022. Her new position became official on November 5, 2023.

Since 2008, Dr. Bailey has been part of OMUMS, where she has served as a regulatory review scientist managing all aspects of the program administering the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. Prior to joining the OMUMS staff, she was a reviewer on the Antimicrobial Drugs Team, Division of Food Animal Drugs in CVM's Office of New Animal Drug Evaluation.

Dr. Bailey received her DVM from the Virginia-Maryland College of Veterinary Medicine. She did her undergraduate work at Clemson University and Sweet Briar College.

Staffing Updates

Thank You, Dr. Anna Nevius!
Dr. Anna Nevius departed OMUMS at the end of 2023 to pursue full-time retirement. We thank her for her energy, tireless dedication, and expertise to our projects, both during her time as a full-time employee and post-retirement, as a rehired annuitant. Best wishes for your next chapter, Anna! You will be missed.

Detailees

Thank You, Dr. Stacey Shults!
In October, Dr. Stacey Shults completed a 90-day detail with OMUMS. During her time with us, she completed several indexing submissions and provided feedback on ways to adopt more plain language in our indexing documents. Her efforts helped improve the current indexing process and meet our review deadlines. Thank you for your contributions, Stacey!

Thank You, Dr. Charles Giesecker!
Dr. Charles Gieseker completed a detail with our office in April. He has been working in CVM's Office of Applied Science since 2001, serving as a research biologist focused on research related to aquaculture within the Division of Applied Veterinary Research. His projects have included developing laboratory fish infection models, drug effectiveness testing, drug depletion studies, pharmacokinetic studies, and standardizing antimicrobial susceptibility tests for aquatic bacteria. Prior to FDA, he worked as a fisheries biologist at the Maryland Department of Natural Resources where he conducted surveys of shellfish and finfish diseases in the Chesapeake Bay. He has a B.S. degree in Fish & Wildlife Management from Frostburg State University, a M.S. in biological sciences from the University of Maryland, Baltimore County, and a PhD in Marine, Estuarine, and Environmental Sciences from the University of Maryland, College Park. We shared the mission and work of OMUMS with him and learned about his work in the Office of Applied Science.

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:

- OMUMS granted a request to modify the index listing for Ethiqa XR® (buprenorphine extended-release injectable suspension). This drug can be used for the control of post-procedural pain in mice, rats, ferrets, and non-human primates.

Photo courtesy of Stuart Jeffrey

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 intended for minor species and minor uses in major species, and awards seven years of exclusive marketing rights to these sponsors once the drug is approved or conditionally approved for the designated intended use.

Currently, we have 169 designations total, including 47 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.

The FDA MUMS Grant Program completed the first of two open periods for MUMS grant applications for Fiscal Year 2024 in July 2023. The Program subsequently awarded two grants, one in the amount of $205,612 and the second for $209,928, to help fund studies to support approval of two designated drug products intended for minor species. Links to information about MUMS grants and how to apply are available on the Drug Designation webpage. The application period for fiscal year 2024 Part 2 closed on February 2, 2024.

To date, the MUMS Grant Program has awarded a total of $7.3 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*	Method validation protocol concurred	*Complete*

Project updates from the MUADP:

- **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 was completed. Also, the program recently received concurrence on a protocol to validate the analytical method for tulathromycin in caprine liver. A validated method is an important milestone in the completion of the Human Food Safety technical section.

The Pets of OMUMS!


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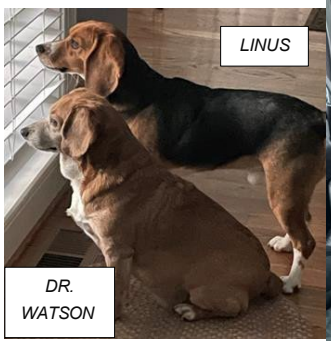
FOSSE


SIRIUS

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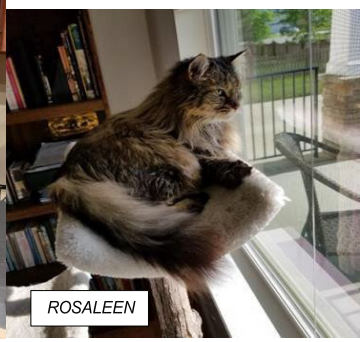
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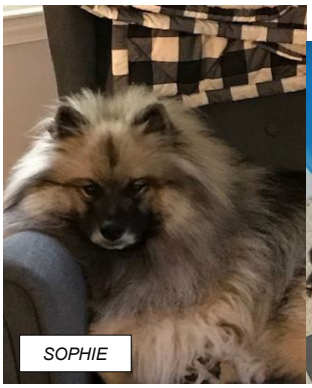
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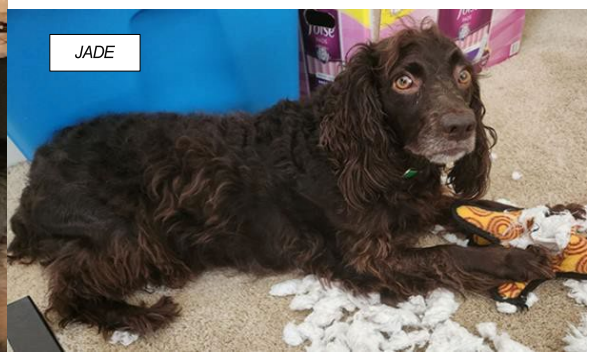
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For further information about OMUMS and our programs, please visit our website.

Contact Us

Dr. Dorothy Bailey, 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