OMUMS Newsletter Fall 2022

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

This newsletter is 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

New Addition to OMUMS!

In July, OMUMS welcomed Dr. Daniel Skirvin. Danny initially began his CVM career in ONADE's Division of Therapeutic Drugs for Non-Food Animals in 2018. Prior to that, he was a veterinarian working in both general practice and emergency medicine treating small animals and exotics for over 10 years. He earned his Bachelor of Science degrees in Entomology and Veterinary Sciences, followed by his Doctorate of Veterinary Medicine from the University of Illinois, Champaign/Urbana. Recently, he also earned dual Master's degrees in Public Health and Business Administration. We are excited to welcome Dr. Skirvin's extensive expertise, experience, and enthusiasm as a Veterinary Medical Officer. He will provide much needed support for the office and our mission. Here he is with his new kittens, Albus and Sirius.

Retirements

After 30 years with CVM, Dr. Meg Oeller will retire at the end of December. She has provided outstanding leadership to our office and tirelessly advocated for our minor use and minor species stakeholders. Meg will be sorely missed.

OMUMS will be getting a new Office Director sometime in 2023. In the meantime, acting Directors will keep things on track.

Anna Nevius also will be retiring (again) at the end of the year. She had a long first career in CVM, and came out of retirement to assist the Center with a variety of issues. We have benefited greatly from her expertise in statistics. For the last few years, she has been vital to the completion of major technical sections for the Minor Use Animal Drug Program. In the coming year, we expect to see needed minor species drug approvals for projects that she helped complete. Thank you, Anna!

Updating Guidance for Industry (GFI) #210

In response to stakeholder concerns, we took a closer look at how we determine eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (The Index). We are in the process of updating the Guidance to reflect our current thinking. You can click the link above to read more about how we got here and our plans going forward.

Revised regulation for defining "small numbers" for use in assessing claims for "minor use" status

FDA Provides for More Treatments for Dogs and Cats to Qualify for Minor Use Status

OMUMS periodically reviews the published "small numbers" that represent the threshold level for "minor use" status in each of the 7 major species. Minor use means that a disease or condition occurs in fewer than a "small number" of animals in the US annually. The current reassessment led us to increase the numbers for dogs (from 70,000 to 80,000) and cats (from 120,000 to 150,000). This means that more diseases or conditions will qualify as rare for these species and more products for those indications will be eligible for incentives to get those products approved. The link above will take you to more information, including the revised regulation and the memo about how the reassessment was conducted.

Status: 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**.

Status: 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 50 active designations (those still pursuing approval = not already approved, conditionally-approved or terminated) on the list. Last quarter we added two designations and terminated two designations.

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

We completed the first of two open periods for MUMS grant applications for fiscal year 2023 in late July. Links to information about MUMS grants and how to apply are available on the Drug Designation webpage. The next open period for applications will be December 2, 2022, to February 3, 2023.

The FDA MUMS Grant Program expects to award one $250,000 grant for the Fiscal Year 2023 Part 1 grant application period.

To date, the MUMS Grant Program has awarded a total of $6.6 million to fund studies that support MUMS drug approval.

Status: 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

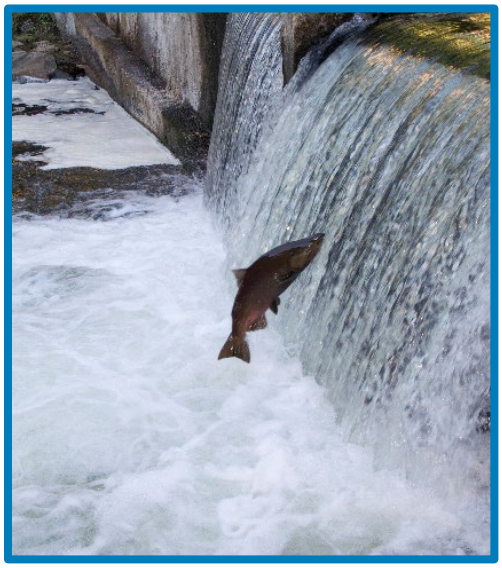
Project	Effectiveness	Target Animal Safety	Human Food Safety	Environmental Impact
Progesterone CIDR for estrus synchronization in goats	Final Study Report pending	*Complete*	*Complete*	*Complete*
Fenbendazole for nematodes in pheasants	*Complete* – Update pending	*Complete*	*Complete*	Categorical Exclusion request pending
Fenbendazole for nematodes in quail	*Complete*	Data submission under review with FDA	*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 in development	*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. With FDA's recent acceptance of a residue depletion study in quail, the **human food safety** technical section is now complete for this project.

  The program recently submitted a margin of safety study in quail for FDA review with the hope that this submission will complete the technical section for **target animal safety**.

- **Tulathromycin for Goats:** The MUADP continues their work on the project to support approval of tulathromycin for the treatment of respiratory infections in goats. In the Summer of 2022, the first of two required effectiveness studies was completed.



For further information about the Office of MUMS and our programs, please visit our website at: **MUMS webpage**

Contact Us

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Starting January 2023

Dr. Dorothy Bailey, OMUMS Acting Director

Dr. Lucy Lee, for Indexing questions

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