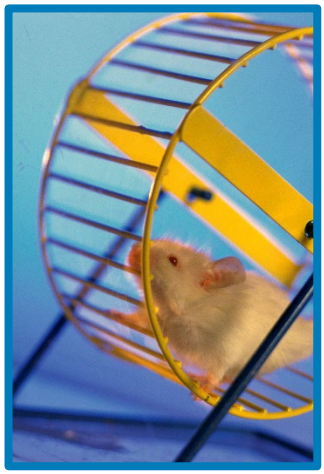

OMUMS Newsletter Spring 2022

Office of Minor Use & Minor Species Animal Drug Development (OMUMS)

FDA Center for Veterinary Medicine

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

Draft Guidance for Industry (GFI) #61 received over 200 comments. We, and our colleagues in the Office of New Animal Drug Evaluation, reviewed them carefully and incorporated many of your suggestions. The final guidance is undergoing review. We will announce the availability of the final document as soon as it is posted. In the meantime, you can click the link above to read the draft version.

Expansion of Indexing Eligibility Questions

We received over 50 comments in response to our 'request for information' to address the question of whether we should expand eligibility for indexing to some groups of animals that have previously been ineligible because they were members of a species that is used as food for people and other animals. These could include laboratory rabbits, broodstock fish, etc.

Ultimately, we will incorporate any new policy into a revised version of our Guidance for Industry #210, "The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species." We will update you as we progress.

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 14 products to the Index. See: **MUMS Indexing webpage**.

Big News – 2 New products added to the Index!

MIF #	Holder	Drug	Species	Use
900-033	Wildlife Pharmaceuticals	MeloxiLab-Rat™ (meloxicam extended-release injection)	Rats	For the control of post-procedural pain
900-020	Wildlife Pharmaceuticals	BupreLab-Mouse™ (buprenorphine hydrochloride extended-release injection)	Mice	For the control of post-procedural pain

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 162 designations total, including 50 active designations (those still pursuing approval = not already approved or terminated) on the list. Last quarter we added two designations and terminated one designation. One designated product was conditionally approved.

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 2022 in early February. 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 May 27 to July 29, 2022.

To date, the MUMS Grant Program has awarded a total of $5.8 million to support studies to 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.

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 submitted a residue depletion study in quail for FDA review with the hope that this submission will complete the technical section for human food 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. MUADP collaborated with researchers from Iowa State University's College of Veterinary Medicine to design a protocol for the required effectiveness study. In early 2022, this effectiveness protocol received concurrence from FDA and the researchers plan to initiate the study in the Summer of 2022.

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*	Final Study Report pending	Data submission under review with FDA	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 – Study to begin Summer of 2022	*Complete*	Protocol in development	*Complete*

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

Contact Us

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