OMUMS Newsletter Fall 2021

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Draft Guidance for Industry (GFI) #61 received many comments. We are in the process of reviewing them and will use much of what we learn to revise the draft before it is finalized. You can click the link to read the current draft document.

We have published a 'request for information' from our stakeholders 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.

To learn more about the issue and to see how to comment, please go to: **Expansion of Indexing Eligibility Questions**

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**.

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 159 designations total, including 52 active designations on the list. Last quarter we added two designations and terminated nine designations. One designated product was conditionally approved. 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 2022 at the end of July. The second open period will run from December 3, 2021 through February 4, 2022. Links to information about these grants and how to apply is available on the Drug Designation webpage.

To date, the MUMS Grant Program has awarded a total of $5.6 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 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 received from FDA a *technical section complete letter for effectiveness*.

- **Tulathromycin for Goats:** The MUADP has resumed work on a project to support approval of tulathromycin for the treatment of respiratory infections in goats. They recently met with FDA to discuss the types of studies and data necessary to complete the effectiveness and target animal safety technical sections. MUADP is partnering with researchers from Iowa State University's College of Veterinary Medicine to design and conduct the required effectiveness study.

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 being prepared	*Complete*	*Complete*	Categorical Exclusion request submitted
Fenbendazole for nematodes in quail	*Complete*	Final Study Report pending	Final Study Report pending	To be addressed by the manufacturing sponsor
Erythromycin for Bacterial Kidney Disease in freshwater-reared salmonids	*Complete* for Chinook	*Complete*	*Complete*	Draft environmental assessment prepared
Tulathromycin for respiratory disease in goats	Protocol in development	*Complete*	Protocol in develop-ment	*Complete*

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