U.S. FOOD & DRUG ADMINISTRATION

OMUMS Newsletter Fall 2020

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

FDA Center for Veterinary Medicine

This newsletter keeps 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

We have published the long-anticipated revision to **Guidance for Industry (GFI) #61** as a draft for public comment. We strongly encourage your feedback. Please click the link to read the document and see how to submit your comments.

The US Fish & Wildlife Service recently hosted the all-virtual **Aquatic Animal Drug Approval Partnership Workshop** for updates to projects seeking FDA approval for products for US aquaculture.

OMUMS participated in two presentations at this workshop – one a general update on our work and the other specifically on the Index of Legally-Marketed Unapproved New Animal Drugs for Minor Species (the Index). These presentations are also on the **MUMS Presentations 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, there are 156 designations total, including 60 active designations for products not approved yet. Last quarter we added one designation and terminated two designations. See the **Drug Designation webpage** for the complete list, including a sortable Excel version.

We recently completed the first of two open periods for MUMS grant applications for fiscal year 2021. The second is scheduled for November 13, 2020 through January 15, 2021. To date, the MUMS Grant Program has awarded a total of $4.9 million to support studies to support MUMS drug approval.

Status: Minor Use Animal Drug Program

The MUADP is a USDA program that provides the scientific data to support FDA approval of new animal drugs for minor species of agricultural importance. Currently, the program is restructuring, but continues to work to complete existing projects. The MUADP uses a Public Master File to contain the information to complete the technical sections for effectiveness, target animal safety, human food safety, and environmental impact. Pharmaceutical sponsors can use this information along with their own manufacturing and labeling to complete a New Animal Drug Application.

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	Final Study Report pending	Final Study Report pending	Protocol development	Categorical Exclusion request submitted
Erythromycin for Bacterial Kidney Disease in freshwater-reared salmonids	*Complete* for Chinook	*Complete* for Chinook	*Complete*	Draft environmental assessment prepared
Tulathromycin for respiratory disease in goats	Protocol in development	*Complete*	Protocol in development	*Complete*

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**.

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