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Alternative Means for FDA Approval of Pet Care Drugs – Part 3: Differences Between Major and Minor Species

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This update is the final in a multi-part series exploring FDA approval of pet care drugs.

In part one of our series we discussed that before an animal drug product can be legally marketed for use in animals, a New Animal Drug Application (NADA) for the drug must be approved by the FDA. If the proposed drug product meets certain qualifications, the FDA may provide a company with the option of seeking conditional approval of the drug.

In part two we examined how Expanded Conditional FDA Approval has the potential to incentivize drug development and provide veterinarians with legally marketed new animal drugs to treat serious or life-threatening diseases or conditions and to fill treatment gaps where currently no therapies are available.

In this final article, we explore the differences between major and minor species, as it applies to the FDA Approval of a new drug.

What are Major and Minor Species?

According to the FDA, dogs, horses, cats, cattle, pigs, turkeys, and chickens are “Major Species.” “Minor species” are all animals other than humans that are not one of the major species. Examples of minor species include zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Additional examples of minor species animals that are considered agriculturally important include sheep, goats, catfish, game birds, and honeybee among others.

What does Minor Use in a Major Species mean?

“Minor use” means the “intended use of a drug in a major species for a condition that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.” The FDA defines a specific “small number of animals” for minor use in each of the major species. For example, a “minor use” for dogs is to treat a condition that affects less than or equal to 80,000 dogs a year in the U.S.

MUMS Act

"The Minor Use and Minor Species Animal Health Act of 2004," often referred to as the "MUMS Act", was signed into law on August 2, 2004. According to the FDA, "The law is intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in the major animal species."

The law modifies the Federal Food, Drug and Cosmetic Act in three keyways to provide for Conditional Approval, Designation, and Indexing:

CONDITIONAL APPROVAL: FDA requirements for a conditionally approved NADA are identical to a fully approved NADA except for the effectiveness section of the NADA has reduced data requirements. Although data requirements to demonstrate effectiveness are reduced for a conditionally approved NADA. NADA requirements to establish safety, and to fulfill manufacturing and product quality standards, are the same for a conditionally approved NADA and a fully approved NADA.

Drug companies can market a conditionally approved drug after proving its safety and a reasonable expectation of effectiveness, while gathering the additional efficacy data required for full approval.

The "conditional" part of conditional NADA approval indicates that the drug sponsor has the responsibility to, within five years, generate the additional effectiveness data required to fulfill the FDA's substantial evidence standard for full NADA approval. If the drug sponsor fails to gather this evidence within five years, conditional approval status of NADA is lost, and the drug product can no longer be marketed.

DESIGNATION:

Modeled after the "Orphan Drug Act" for humans, designation encourages pharmaceutical sponsors to develop drugs for rare diseases, sponsors of "designated" new animal drugs are eligible to apply for grants to support safety and effectiveness testing. They are also eligible to apply for waivers from user fees.

A sponsor that gains approval or conditional approval for a designated new animal drug receives seven years of exclusive marketing rights, facing no competition from another sponsor marketing the same drug in the same dosage form for the same intended use for that time.

INDEXING:

According to the FDA, "a minor species drug is intended for use in species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of a drug approval." When this happens, the FDA may add the intended use to the "Index of Legally Marketed Unapproved New Animal Drugs for Minor Species" (the Index). This provision is especially helpful to veterinarians treating zoos or endangered animals - or classes of animals including numerous different species, such as ornamental fish. Only minor species that are not used as food for

humans or other animals can be included.

Conclusion

Innovative drugs often mean new treatment options for veterinarians and their clients along with advances in health care for major and minor species. The MUMS Act revises the “small number of animals” definition for dogs and cats for purposes of qualifying drugs for “minor uses”, increasing from 70,000 and 120,000 to 80,000 and 150,000, respectively. This increase opens the door to more MUMS Act-eligible treatments for those two species.

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