Holland & Hart

Alternative Means for FDA Approval of Pet Care Drugs - Part 1: Conditional Approval



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

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 U.S. Food and Drug Administration (FDA). If the proposed drug product meets certain qualifications, the FDA may provide a company with the option of seeking a conditionally approved NADA.

To understand the FDA approval process for a new animal care drug, we must first understand the term “drugs.” The Federal Food, Drug and Cosmetic Act (FFDCA) defines the term “drugs” to include, among other things, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

The FFDCA gives the FDA the legal authority to approve and regulate drugs for both people and animals. A drug intended for use in animals is called a “new animal drug”. The FDA's Center for Veterinary Medicine (CVM) approves and regulates new animal drugs.

The Role of the Drug Sponsor

Let's define “drug sponsor.” A drug sponsor is the entity responsible for collecting all the information about a new animal drug and submitting this information to CVM for review.

Any organization, or even one person, can be a drug sponsor. For example, scientific research groups, government agencies (such as the U.S. Department of Agriculture) and academic organizations (such as colleges and universities) can all be drug sponsors. But typically, drug sponsors are pharmaceutical companies.

The drug approval process starts with the drug sponsor. The sponsor conducts initial research on a potential new animal drug, and if the research is promising, the sponsor contacts CVM to start discussions about the drug and the approval process.

The drug sponsor is responsible for testing a new animal drug for safety and effectiveness. CVM reviews the results of the tests to determine if the

drug is safe, effective, and meets the approval requirements.

Typically, new animal drugs go through the NADA process to obtain FDA approval prior to marketing. The NADA process is fairly like the new drug approval process for human drugs and is time-consuming and expensive. However, there are two alternative means of getting your product approved: (1) conditional approval and (2) expanded conditional approval. In this article, we're going to focus on conditional approval.

Conditional Approval

FDA requirements for a conditionally approved NADA are identical to a fully approved NADA except for the effectiveness section of the NADA, which has reduced data requirements. Although data requirements to demonstrate effectiveness are reduced for a conditionally approved NADA, it is important to note that a significant body of evidence is still required to establish a reasonable expectation of the product's effectiveness. 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.

Typically, conditional approval applies to drugs that are either (1) for a “major species” for a “minor use” or (2) for a “minor species.” The FDA considers dogs, horses, cats, cattle, pigs, turkeys, and chickens “major species.” A “minor use” means the “intended use of a drug in a major species for an indication 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.” 21 CFR 516.3. 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 US.

Conditionally approved drugs are designated by the abbreviation “-CA1” after the drug name.

Are Conditionally Approved Drugs Any Less Safe than Fully Approved Drugs?

A common misconception is that conditionally approved drugs aren't as safe as fully approved FDA drugs—that is not the case. Although additional data is required to fulfill the effectiveness standard for full NADA approval, the FDA's approval of a conditionally approved product

demonstrates that all NADA requirements for safety and manufacturing have been fulfilled. Additionally, the FDA grants conditional approval based on data that demonstrates that the product's formulation is manufactured in a manner that ensures that the product will be safe and effective when used as directed in the product's labeling.

Applying for Conditional Approval

To seek Conditional Approval or Expanded Conditional Approval, the first step is to identify the “sponsor.” A veterinarian may be a good candidate to serve as sponsor. After that, the required data must be collected. The sponsor will need to submit two copies of a completed, dated, and signed request for designation that contains:

1. A request for designation of a new animal drug for minor use.
2. The name and address of the sponsor and other identifying information.
3. The established name of the active pharmaceutical ingredient of the drug.
4. The name and address of the source of the active ingredient.
5. A description of the proposed intended use.
6. A description of the drug and dosage form.
7. A discussion of the scientific rationale for the intended use of the drug (including data from nonclinical laboratory studies, clinical investigations, copies of unpublished and published papers, and other relevant data—whether positive, negative, or inconclusive.)
8. A description of the product development plan.
9. Documentation demonstrating that the intended use is a minor use, including:
    a. the estimated total number of animals to which the drug could potentially be administered on an annual basis for the treatment of the disease or condition
    b. a list of the sources supporting the estimated total number of animals
    c. a statement that the sponsor submitting the application is a real party in interest of the development and intended production and sales of the product; and
    d. a statement that the sponsor acknowledges that, upon granting a request for this conditional approval process, the FDA will make information concerning the designation publicly available.

Conclusion

Gaining full FDA NADA approval of a new animal drug is time-consuming and expensive. By exploring conditional approval as a means of getting a product approved, the drug sponsor can gain more time to collect the effectiveness data needed to apply for full drug approval, while offering their product for sale on the marketplace.

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