FDA Study Aims to Eliminate Use of Dogs in Certain Trials

A non-animal based model could potentially help replace dogs in future trials with new informatics tools.

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Statement by FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce animal testing through a study aimed at eliminating the use of dogs in certain trials

The U.S. Food and Drug Administration is committed to animal welfare in research by reducing, replacing and/or refining the use of animals in research, whenever possible. We're taking a step today to propose a study that, once completed, could provide a way for animal drug developers to conduct certain types of research without the use of dogs.

The aim is this: by doing a single study to help establish a non-animal based model, we can potentially replace much of the need to use dogs in future trials with new informatics tools. In short, our goal is to do one single study involving a small number of dogs—where the dogs will only be subject to minimally invasive blood sampling, and adopted as pets at the completion of the short trial—to eliminate the need for the use of dogs in certain types of future studies, some where they might have been euthanized.

The proposed study we are announcing today is part of the FDA's overall efforts to help reduce reliance on animals used for research conducted by the agency's scientists, as well as research conducted by industry. In fact, if validated, this study could provide a new tool for animal drug developers to use in their own research for certain products and help them generate data in support of applications submitted to the agency without the use of animals. This is one example of several activities that the FDA is conducting to help provide industry with modern approaches to data generation that do not require the use of animals.

The agency is optimistic that cultivating these types of new research approaches can help continue to reduce the need for animal testing.

A critical element of the FDA's mission is to help ensure that any products we approve are safe and effective for those who will ultimately use them. This is the approach we take for the approval of animal and human drugs. Before approving an animal drug, the FDA must have data to understand how a drug behaves in an animal's body. As one part of generating these data, animal drug developers perform bioequivalence studies, which compare pharmaceutical products (i.e., an

original approved product and proposed generic version) to see if they are similar enough to link them in terms of safety and effectiveness.

Specifically, the goal of the study we're proposing today is to validate a research model for the comparison of blood levels of certain orally-administered canine drugs, in order to provide an alternative approach that animal drug developers can use to generate data needed to support the FDA's approval of these types of drugs without the use of dogs during the research process. We're accepting public comment on a white paper outlining this proposed study for the next 60 days.

Our study would compare the bioequivalence of tablets containing both locally and systemically acting antiparasitic drugs that are already widely used in dogs and well-tolerated. Drugs that act locally are not absorbed into an animal's blood stream, while systemically acting drugs are absorbed into the blood stream. For antiparasitic drugs that act locally within the gastrointestinal tract, this has historically required data gathered from terminal studies, meaning the animals were artificially infected with gastrointestinal parasites and then euthanized at the conclusion of the study so that researchers could physically examine the GI tract for parasites or parasite damage, to evaluate whether the drug was effective. The goal of the model we're aiming to develop is to reduce or eliminate these research practices.

In our study, no dogs would be euthanized. Instead, the proposed study would place dogs into three groups and, over the course of several months, they'll receive a total of three pills. After each pill is administered, our researchers will draw a small amount of blood from the dogs at specified intervals to measure the concentration of the drugs in the blood and compare them against existing data for these products.

By using the data we generate from these blood tests to establish a clear benchmark for how these drugs are absorbed in the dogs' blood, we expect to be able to use these data to develop informatics tools that can model the absorption of drugs in the future, rather than requiring the drugs to be tested on live dogs.

Because we know that it's important to prepare the dogs to be calm for their blood draws, and to give them a head start on their transition to life as pets, the research staff will work with the dogs to socialize and acclimate them to their environment for at least two months before this study begins. The dogs will receive regular veterinary care, including vaccinations and other preventive care, so that they remain happy, well-socialized and healthy. At the conclusion of the study, the dogs will be retired for adoption as pets.

The FDA is dedicated to providing the utmost care for all animals used as part of our research. In January 2018, the agency established a new Animal Welfare Council to provide centralized oversight of all animal research activities and facilities under its purview. This council advises the agency on its approach to animal welfare issues and ensures alignment of animal studies with the agency's mission.

While we understand that in certain situations the use of animals in research is needed, we're committed to exploring ways to help FDA scientists and product developers reduce reliance on this

practice. This proposed study is a big part of that effort.

In addition to the study being proposed today, we have already taken significant steps to reaffirm and strengthen our commitment to replacing, reducing, and/or refining animal studies and support the development and use of alternative methods (such as assays and technologies like organs-on-a-chip). We've formed the Modeling and Simulation Working Group to accelerate the adoption of modeling and simulation tools in product development and evaluation; and initiated the Toxicology Working Group, which has developed a roadmap for integrating emerging predictive toxicology methods and new technologies into regulatory safety and risk assessments. The FDA also participates in and chairs the Interagency Coordinating Committee on the Validation of Alternative Methods.

As we continue to advance new innovations for animals and people, we're interested in learning about other new technologies that can reduce, replace and/or refine the need for animal testing.

We look forward to working with drug developers and other stakeholders to achieve these goals while fulfilling our important public health mission.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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