



# ***FDA VETERINARIAN***

## **FDA's Regulation of Pet Food**

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This article describes the role of the Food and Drug Administration (FDA) in the regulation of pet food. FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (the Act.) Under the Act, a part of FDA's responsibility is to ensure that human and animal foods are safe and properly labeled. Within FDA, the Center for Veterinary Medicine is responsible for the regulation of animal drugs, medicated feeds, food additives and feed ingredients. The regulations based, in part, on this law are found in the Code of Federal Regulations, Title 21, Food and Drugs, Part 500.

The Act is this country's basic food and drug law. It defines food as "articles used for food or drink for man or other animals...and articles used for components of any such article." There is no requirement that pet foods have pre-market approval by FDA. The Act does require that pet foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled. Additionally, canned pet foods must be processed in conformance with low acid canned food regulations (Title 21, Code of Federal Regulations, Part 113, abbreviated as 21 CFR 113).

In the Act a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article intended to affect the structure or function of the body other than food (Sec. 201 (g)(1)). In the drug definition, the courts have interpreted "food" as something that provides nutrition, taste or aroma. If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure or taurine for healthy heart function in cats.) However, if a product affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug. Structure/function effects extending beyond the "food" umbrella also include claims for improved or increased production and performance, or alteration or improvement in function.

When a substance, including one considered food, is intended to be used for the treatment or prevention of disease or "non-food" structure/function effect, it "becomes" a drug. Under the law, a new animal drug must be shown to be safe and effective for its intended use by adequate data from controlled scientific studies as part of a New Animal Drug Application (21 CFR, Part 514). If a product on the market is not approved, it may be deemed an adulterated drug and subject to regulatory action.

In 1958, in response to public concern about the increased use of chemicals in foods and food processing, Congress amended the Act to require the pre-marketing clearance of additives whose safety was not generally recognized. The Act was also amended to deem food unsafe and adulterated if it contains an unapproved food additive. Under the definition for food additive in Sec. 201 (s) of the Act, it provides that substances added to food which qualified scientists generally recognize as safe (GRAS) under the conditions of their intended use are not "food additives" and as such are exempt from pre-clearance approval.

A food additive petition is the pre-clearance mechanism developed by the FDA for demonstrating that a food additive is safe for its intended use and has utility. If the FDA agrees with the petition, a regulation is published in the Federal Register and 21 CFR, Part 573, Food Additives Permitted in the Feed and Drinking Water of Animals, is amended. The information needed in a food additive petition is described in Part 571 of Title 21. Briefly, a petition contains a description of the chemical identity, manufacturing process and controls, analytical methods, utility data, human food safety data, target animal safety data, product labeling, and in some cases an environmental assessment.

CVM has used regulatory discretion and not required food additive petitions for substances that do not raise any safety concerns. In this case, we ask the company to submit the information needed to list the ingredient in the Official Publication of the Association of American Feed Control Officials (AAFCO). This ingredient definition process is done to conserve agency resources, as food additive approval is time-consuming. CVM reviews the data to ensure the ingredient has utility and can be manufactured consistently to meet product specifications.

Although ingredients used under regulatory discretion are still unapproved food additives, we agree we will not take regulatory action as long as the labeling is consistent with the accepted intended use, the labeling or advertising does not make drug claims, and new data are not received that raise questions concerning safety or suitability.

A GRAS substance is GRAS only for an intended purpose. For example, sodium aluminosilicate is GRAS as an anticaking agent. It has been purported to bind mycotoxins and prevent absorption from the intestinal tract but would not be GRAS for this use. A food substance also cannot be GRAS for the prevention, treatment, or mitigation of a disease. So, chondroitin sulfates cannot be GRAS to prevent or treat arthritis. For this use it would be a drug.

It is very important to recognize that general recognition of safety of a substance for an intended use may only be based on the views of experts qualified by scientific training and experience to evaluate the safety of the substance. As interpreted by FDA and the courts, there are two requirements that must be satisfied before a substance can be GRAS; general recognition and safety:

1. For general recognition, there must be an expert consensus that the substance is safe for use as a component of food, and;
2. This expert consensus of safety must be based on either (a) generally available data and information to show common use of the substance in animal feed prior to 1958 or (b) scientific procedures, which require the same quantity and quality of

scientific data needed for FDA approval of the substance as a food additive. In addition, this information must be published in the scientific literature.

Both of these requirements, general recognition and safety, must be met for a substance to be considered as GRAS. The GRAS standard is actually more stringent than that required for a food additive approval because for a substance to be GRAS there must exist the same quality and quantity of information needed for a food additive approval, and in addition, the data must be published and there must be a consensus among qualified experts, based on the data, that the substance is safe for that use. Publication of data in a company's annual report does not meet the publication standard. For general recognition of safety to exist, the data must be available to the experts by publication in the scientific literature. The Act permits companies to make their own GRAS determination, and many times, GRAS Panels will be assembled that are comprised of scientific experts in a particular field to evaluate the safety of a substance for an intended use. However, regardless of who makes the determination, the FDA or the company, the standard for GRAS is the same.

On April 17, 1997, the Center for Food Safety and Applied Nutrition (CFSAN) and (62 FR 18938) CVM published a proposed rule in the Federal Register to amend the regulations to replace the current GRAS affirmation process with a notification procedure. Under the notification procedure, any person could notify the agency of a determination that a particular use of a substance is GRAS. The notification would include a description of the substance, the conditions of use, and the basis of the GRAS determination. The FDA would not conduct its own detailed evaluation of the data, as was done previously for GRAS Affirmation petitions. Rather, FDA would evaluate whether the notice provides sufficient basis for a GRAS determination and whether the information in the notification or otherwise available to FDA raises issues on whether the use of the substance is GRAS or not. In the proposal FDA would have 90 days to respond to the notifier. The summary of the GRAS notifications would be available on the FDA homepage, as would the FDA's responses to the person submitting the notification. CVM is not currently accepting GRAS notifications under the proposed rule; however, CFSAN is. A [listing of the notifications](#) that have been submitted can be found on our website.

Once the final rule is published, CVM will accept GRAS notifications. It is anticipated that GRAS notifications submitted for use of substances in animal feed will be posted on the CVM homepage. When a GRAS notification raises no issue of concern to CVM, the AAFCO Feed Ingredient Chair will be notified so that the substance and its use can be listed in the AAFCO publication.

### ***The Dietary Supplement and Health Education Act***

When Congress enacted the Dietary Supplement and Health Education Act (DSHEA) on October 25, 1994, it created a new category of substances and new regulatory scheme. The Act was amended to define a dietary supplement as a product intended to supplement the diet and that contains at least one or more of the following ingredients: a vitamin; a mineral; a herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of the previously mentioned ingredients (Sec. 201 (ff) of the Act). The main effect of DSHEA was to remove certain dietary ingredients from regulation as food additives, which requires pre-market

approval. On April 22, 1996, CVM published a notice in the Federal Register outlining the reasons why FDA believes that Congress did not intend DSHEA to apply to products for use in animals. This has been upheld in at least one court case. Thus, products marketed as dietary supplements for humans still fall under the pre-DSHEA regulatory scheme when marketed for animals, that is, they are considered food, food additives, new animal drugs, or GRAS depending on the intended use. For most of these types of products on the market they would be considered unapproved and unsafe food additives or new animal drugs based on current intended use.

It is important to note that DSHEA defines the term "dietary supplement" to exclude products intended for use as conventional foods. For example, St. John's Wort would not be considered a dietary supplement if it were added to soup. Soup is a conventional food and any ingredient added to conventional foods must be used in accordance with the food additive regulation or be GRAS. Similarly, if DSHEA was extended to include pet food, chondroitin sulfate added to pet food would not be permitted under DSHEA. Chondroitin sulfate would be an unapproved food additive for this use.

### ***Health Claims***

Congress also amended the Act, when it enacted the Nutrition Labeling and Education Act in 1990. This law required FDA to write regulations to permit health claims on human food. A number of these claims have been approved for various foods, the latest being the claim approved by FDA on October 26, 1999, for soy protein as follows:

**Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides \_\_\_\_ grams of soy protein.**

CVM has incorporated the philosophy of NLEA in its policies in order to permit meaningful health information on pet foods. Examples are the use of urinary health tract claim on cat food diets, and development of AAFCO regulations for light, lean, less or reduced calories, lean, and less or reduced fat. Recently, CVM has been asked about complete cat foods for the control of hairballs. We would likely not take regulatory action provided the effect is achieved by ingredients already permitted for use in cat food, such as fiber sources. In this case, we ask that the firm submit information for review on the quantitative diet formulation, nutrient analysis, and labeling, and discussion on the basis for the claim, i.e. scientific studies or common knowledge of ingredients biological properties. If novel ingredients are used to achieve the effect, then we believe data demonstrating ingredient safety should be obtained prior to marketing.

### ***Interaction with AAFCO***

FDA also plays an active role in pet food regulation in partnership with AAFCO. A FDA representative serves on the AAFCO Board of Directors. FDA has served on the Pet Food Committee. CVM staff also serves on other standing AAFCO committees and as investigators. We believe that continued partnership with AAFCO is vital to the continued regulation of pet food products because FDA has limited enforcement resources that are focused on human food safety issues. For this reason, an important role of CVM staff is to serve as scientific resources for state regulatory officials.

### *Summary*

In summary, within the FDA, CVM has primary responsibility for enforcing the Act to ensure that animal foods, including pet foods, are safe and labeled appropriately and animal drugs are safe and effective. While FDA has tried to incorporate some of the philosophy of NLEA to permit health claims for pet foods, we believe that DSHEA was not intended by Congress to apply to animal foods. Thus, products sold as dietary supplements for humans may not be legally distributed for use in animals unless the substances are food, approved animal food additives, GRAS or approved new animal drugs. CVM works in partnership with AAFCO to ensure continued regulation of pet foods and serves as scientific resources to State regulatory officials.