

Pet Food Labels for Special Use Foods

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Treats and Chews

Snacks and treats for pets are implicitly intended to be offered on an occasional basis, and by no means should be fed as the mainstay of the diet. Although pet treats must meet all the other FDA and state regulations for labeling of pet foods, they are exempt from the need to include an AAFCO nutritional adequacy statement. "Biscuits" are not exempt, unless they are identified as a "snack" or "treat" as well. Regardless, some treats and biscuits are formulated to be nutritionally complete, and some are not.

Dog chews made from rawhide, bone or other animal materials or parts (for example, pig ears) are still considered "food" under FDA law, since they are comprised of materials that are consumable by the pet. As long as the label for the chew does not include any reference to nutritional value (such as "high protein"), it may not have to follow the AAFCO pet food regulations. Thus, many labels for chews may not have a guaranteed analysis or follow the AAFCO rules for product names. However, they should still bear the information required under FDA regulations, such as the net quantity statement, the manufacturer's name and address, and the ingredient list (if it contains more than one ingredient or the single ingredient is not declared in the product name). For products sold in bulk, the required information should appear in a placard on the bin or container.

Health Claims

Many of the products intended for special uses involve the dietary management of a disease or condition. Recent laws have affected the way FDA regulates these types of products for human consumption. The Nutrition Labeling and Education Act (NLEA) provides for specified "health claims" (claims that state that consumption of a food may help in the reduction of risk for disease) to appear on human food product labels. The Dietary Supplement Health and Education Act (DSHEA) has allowed for the boom of dietary supplements available for human use, many which include claims of "nutritional support" for specific organs or body functions. Since pet foods follow many similar marketing trends to foods for human consumption, it is not surprising that many pet food and supplement labels also bear these types of claims. However, since the rules for pet foods are very different, some of these claims are not legally allowed.

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines "food" as an article used for food or drink for man or other animals. On the other hand, a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article (other than food) intended to affect the structure or function of the body of man or other animals. "Food," in the parenthetical "other than food," has been further interpreted by the courts as a substance that provides "taste, aroma, or nutritive value." 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.

The legal definitions of food and drug become intertwined when a food label bears a claim that consumption of the product will treat, prevent, or otherwise affect a disease or condition, or to affect the structure or function of the body in a manner distinct from what would normally be described as from its "nutritive value." Also, implied drug claims may include a discussion of a medical condition, reference to an equivalent drug product, or the presence of medical symbols. Such claims establish an intent to offer the product as a drug (i.e., it makes a "drug claim"). Furthermore, since the product was not subject to the normal premarket clearance mechanism to demonstrate safety and efficacy as required for drugs, it is unsafe by definition. Pet food products with labels bearing drug claims are subject to regulation by CVM as drugs as well as foods. A pet food company must then remove these claims to restore its regulatory status to simply food.

FDA's authority to prohibit drug claims extends beyond what is commonly considered the product "label." The FFDCA defines "labeling" as all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or

accompanying such article. Thus, brochures, flyers, signs or similar promotional material found at the point of sale may be labeling and subject to the same laws. Also, although food advertising is not regulated by the FDA, but by the Federal Trade Commission, FDA does have some authority. Advertisements or even verbal representations that establish the "intended use" of the product can be used as relevant evidence that it is a drug.

FLUTD Products

CVM has incorporated some of the philosophy of NLEA in its policies in order to allow meaningful health-related information on pet food labels. Much of CVM's efforts to date have focused on label claims related to cat foods and the prevention of Feline Lower Urinary Tract Disease (FLUTD). Although FLUTD occurs in less than 1% of cats, it is a concern for cat owners. The exact causes of FLUTD are still unclear, and a number of dietary and non-dietary factors may be involved.

Label claims to prevent or reduce the risk of FLUTD, cystitis, urinary problems or similar verbiage are drug claims and are not allowed under the law. However, in an effort to get some meaningful health-related information to the consumer, CVM is exercising regulatory discretion in not taking action against products that bear claims akin to "reduce urine pH to help maintain urinary tract health" or to have low magnesium levels. With respect to urine pH claims, this discretion is contingent upon adequate controlled studies to demonstrate that consumption of the product results in an appropriately acidic urine. Since too much acidification of the urine can also result in serious health problems, data to demonstrate safety of the product are reviewed as well. With respect to dietary magnesium levels, the "cut-off" criteria to support a "low magnesium" claim are less than 0.12% on a dry matter basis and less than 25 mg per 100 kilocalories of metabolizable energy. Companies submit the results of proximate analyses (including crude protein, crude fat, crude fiber, moisture, and ash) and magnesium analyses of a number of production runs of the product. Demonstration that the product formulation consistently meets the cut-off criteria supports the label claim. The estimation of magnesium content as calculated by using guaranteed analysis values on the product label must also meet the criteria.

In order to be most useful in reducing the risk of FLUTD, products must also be used correctly. If the product is mixed with other foods or "meal fed" (offered for only a short period of time per day), it might not be able to maintain the proper urine pH to be beneficial. Thus, feeding directions are added to recommend the product be fed alone and to be made available throughout the day. Also, the nutritional adequacy statement on the label must be for adult maintenance only. This disease occurs primarily in young to middle-aged adults, and the most serious problems occur in males. Since the safety of these products for kittens and pregnant or nursing queens has not been established, it is recommended not to use these products for these life stages.

Another FLUTD-related claim, "low ash," is not allowed on cat food labels. The current scientific consensus is that ash per se is not related to the incidence of FLUTD. There are no valid reasons to reference ash on the product label (other than in the guaranteed analysis) except in regard to this outdated theory. Thus, "low ash" or similar claims, even without reference to FLUTD, are inherently false and misleading, which render the product misbranded and subject to regulatory action.

Weight Control Products

Obesity in pets is probably the most common nutritional problem today. Reduced calorie products have been on the market for many years. However, following the lead of marketing niches for human foods, more and more "lite" pet food products are now available. FDA regulations promulgated under the NLEA established the rules for human products labeled as "lite," "low calorie" or similar terms, but do not apply to pet foods.

Recent AAFCO regulations governing the use of terms such as "lite" became effective this year. Under the new rules, the term "lite" must be based on a standard reference for all products, regardless of manufacturer. For example, a "lite" or "low calorie" dry dog food cannot contain more than 3100 kilocalories per kilogram (kcal/kg), while a similarly named dry cat food cannot contain more than 3250 kcal/kg. Canned foods contain much more moisture, so the maximum allowable calories are even lower (900 and 950 kcal/kg for dog and cat foods, respectively).

For products that are reduced in calories but not enough to merit a "lite" claim, the rules also allow for comparative claims. For

example, if a company makes a very high calorie product and a lower calorie alternative, it can still make statements such as "25% less calories than our regular product." A calorie content statement must also appear on any product bearing a calorie-based claim. In addition to "lite" and "low calorie" claims, a similar set of rules were established for "lean" and "low fat" products, except based on maximum allowable fat percentages instead of calories.

A successful weight loss program takes owner involvement, too. Even a "lite" food can cause weight gain if fed to excess. Owners should follow the feeding directions suggested for weight loss, be careful not to give their pets snacks or table scraps, and even institute an exercise program as the pet's health dictates. Involvement of the veterinarian in the process is also the most prudent in ensuring both the success of the weight loss program and avoidance of potential health risks.

Dental Products

Label claims for "clean teeth" have been on pet food labels for many years, particularly on dry, hard biscuit products. As the field of veterinary dentistry and the awareness of the importance of proper dental hygiene have grown, a number of products have borne much more explicit claims. Claims to treat or prevent gingivitis or periodontal disease are drug claims and should not appear on pet food labels. Plaque or tartar control claims may also be implied drug claims, as they directly relate to dental disease. However, CVM has exercised some regulatory discretion with respect to plaque and tartar claims for products that achieve their effects by mechanical actions. The Veterinary Oral Health Center, an outside organization formed under the auspices of the American Veterinary Dental College, has developed an experimental protocol for companies to follow to demonstrate that their products are useful in reducing plaque and tartar. This organization will also review data from companies to verify that the claim is true, and if so, allow them to carry its logo on the package. CVM has worked with the Veterinary Oral Health Center in this process, so consumers can be assured that products that bear the logo are useful for plaque and tartar control.

Skin and Coat Products

Pet food labels abound with promises for "healthy skin" and "glossy coat." Any normal animal receiving adequate nutrition through use of a complete and balanced product should have these qualities. However, claims to uncategorically "improve" skin and coat or to cure or prevent disease signs such dry skin, flaky skin, or itching may be drug claims.

Perhaps most notorious is the claim for a product to be "hypoallergenic." Elimination diets are used by veterinarians in the diagnosis and management of food allergies. An elimination diet is one devoid of food ingredients likely to cause an allergy, often characterized by itchy, inflamed skin. Resolution of these clinical signs while the animal is on the diet is diagnostic of a food allergy, and trial and error then could be used to determine exactly to what the pet was allergic and what ingredients to avoid. Traditionally, lamb and rice was used as the elimination diet. There is nothing special or unique about these ingredients in terms of allergenicity, and prolonged exposure to these ingredients could also induce an allergic condition. However, they were historically novel sources of protein, since the use of these ingredients was uncommon in commercial dog foods. As such, a pre-existing allergy to lamb or rice would be unlikely.

In recent years, a plethora of products containing lamb and rice entered the consumer market. Many of these products were labeled as "hypoallergenic," or otherwise espoused the benefits of lamb and rice in the treatment or prevention of food allergies and other skin problems. Such claims were made even for products that contained other sources of protein that would disqualify them as effective elimination diets.

CVM does not object to the use of lamb or rice in pet foods. Foods that contain these products in sufficient quantities to meet AAFCO labeling criteria may make claims to the presence of these ingredients. However, any claim to be "hypoallergenic," or any other expressed or implied claim relating these ingredients with benefits to the skin and coat beyond their normal nutritive value is a drug claim.

The same may also be true of other ingredients. For example, many fat sources may contain substances known as omega-3 fatty acids. There are some studies in the veterinary literature to suggest that when used pharmacologically, these substances may have an effect on inflammatory skin disease. However, omega-3 fatty acids are not recognized as essential nutrients at this time.

In other words, dogs and cats cannot have an "omega-3 fatty acid deficiency," and unqualified claims relating to omega-3 fatty acid content may falsely imply nutritional benefit where none has been established. Thus, if a product label bears a claim for omega-3 fatty acids, it must also guarantee its level in the product, accompanied by a disclaimer that it is "not recognized as an essential nutrient by the AAFCO (Dog or Cat) Food Nutrient Profiles."

Veterinary Medical Foods

A "medical food" was originally defined in the Orphan Drug Act as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on sound scientific principles, are established by medical evaluation." Historically, even though medical foods are specifically intended for use in disease conditions, they were regulated by FDA as foods, not drugs. This was because the market for medical foods was relatively small, confined mainly to products such as infant formulas designed for babies with rare genetic conditions. Since the cost of obtaining a drug approval for the product grossly outweighed any profit manufacturers could expect from use in such limited circumstances, FDA allowed this exemption so that the products could be available for those who needed them.

The definition cited above is in reference to foods for human consumption. However, it could also apply to a category of foods for veterinary use that can be characterized as "veterinary medical foods" ("VMF"). These products are generally intended to be offered as the sole source of nutrition to animals with specific medical conditions. Historically, they usually contained restricted amounts of certain nutrients to aid in the mitigation of some disease processes. For example, low protein/low phosphorus diets could be used for some forms of kidney disease, while a low sodium diet could be helpful in some forms of heart disease.

These products are often identified on the market by the label bearing the phrase "use only as directed by your veterinarian," and are often sold only by veterinarians.

As foods, VMF are subject to the same labeling requirements as are any other pet food. As such, labels may not bear drug claims. This restriction also applies to product names. Thus, these products are often given names that would not be easily recognized by the average consumer, such as initials or numbers. Also, VMF labels must meet the same criteria for substantiation of nutritional adequacy as other pet foods. Previously, foods labeled "for veterinary use" were exempt from meeting other AAFCO requirements for "complete and balanced" foods. This appeared contradictory, since assurances of nutritional completeness take on even greater significance when used on sick animals. This fact has been borne out by several well-publicized incidents of nutritional deficiencies in animals fed VMF (for example, taurine and potassium deficiencies were discovered in cats on VMF). Thus, products must now substantiate adequacy by meeting the AAFCO nutrient profile or passing an AAFCO feeding trial protocol for adult maintenance, or include the phrase "for intermittent or supplemental feeding only." Some companies have attempted to circumvent these requirements by listing "intermittent use" on the label, but claiming complete nutritional adequacy in brochures or other sources. Regardless of what the brochures say, if this last statement appears on the label it means that the product has not been shown to be complete and balanced for the normal animal. Thus, it should be used only for certain medical conditions as directed by a veterinarian. Directions for use are presumed to be provided by the veterinarian to the pet owner, so VMF labels are exempt from the AAFCO requirement to include feeding directions.

Labeling of VMF with statements regarding their use in the mitigation of disease processes would imply therapeutic use and thus is not permitted. However, CVM recognizes that VMF have a scientifically sound basis, and they serve a purpose. Thus CVM generally exercises regulatory discretion with respect to distributing truthful information on VMF in materials intended only for veterinarians. Proper use of these types of products requires adequate veterinary supervision. An owner who feeds a VMF product for its desired therapeutic effect solely on the basis of labeling or advertising claims may cause harm resulting from improper diagnosis or treatment.

Dietary Supplements and "Nutraceuticals"

With the availability of today's "complete and balanced" products, nutritional supplements are needed only in very rare circumstances. Injudicious use of supplements runs a greater risk of causing dietary imbalances or toxicity than it does to actually improve the diet. Therefore, unless the pet is being fed a homemade diet that requires additional sources of certain

nutrients, or unless a veterinarian diagnoses a medical condition that could benefit from supplementation, it is best not to give supplements to pets.

"Dietary supplements" describe a much broader range of products. Some provide essential nutrients, such as vitamins and minerals, but others contain substances that are not recognized as essential for the intended species (for example, vitamin C for dogs and cats, omega-3 fatty acids). Herbs, plant or organ extracts, enzymes, and a host of other substances are also often marketed as dietary supplements. The market for dietary supplements was boosted by passage of DSHEA. This law changed the way FDA regulated these products for humans. Briefly, it said that FDA could not call a substance a "drug" or "food additive" if it met the definition for a dietary supplement and was not already regulated as a drug or food additive. Thus, it shifted the burden of the manufacturer having to prove a product was safe before it went on the market to the FDA having to prove it was unsafe before it could be removed. This prompted a sizable increase in the number and range of dietary supplements available on the market today.

DSHEA only applies to human products, not pet products. Some of the substances allowed for sale as human dietary supplements may not be legally permitted to be sold for animals. Although some of the supplements, such as herbal products, may have "thousands of years of history of safe use," this does not include history of use in animals. Animals may react very differently to substances than people, and even small doses can cause adverse effects. For example, aspirin and chocolate, both substances that are used by people every day without ill effect, can be toxic to pets and even cause death. Therefore, since it's not known what the true effects an herb or other supplement may have on pets, it's safest not to allow marketing for that use.

On a case-by-case basis, CVM has reviewed safety information for some substances and allowed them to be used in animal feeds (for example, L-carnitine in dog foods), even though they were officially "unapproved food additives." If included in a pet food or supplement, they must be properly declared on the label. If the substance is not an essential nutrient, the disclaimer "not recognized as an essential nutrient by the AAFCO (Dog or Cat) Food Nutrient Profiles" must also appear on the label.

The term "nutraceuticals" was coined to describe the increasing number of products offered for the prevention or treatment of disease but marketed under the guise of dietary supplements. The promise of a "safe" and "natural" remedy for disease is very appealing. However, since the product has not undergone the same testing for safety and efficacy as required for approved drugs, it's impossible to know whether the product works at all or is even unsafe. Presently, these substances are drugs if the labeling bears claims to treat or prevent disease, or if the intended use as a drug can be established by other means.

Summary

An informed consumer is the best consumer. It is easy to be confused by all the claims and promises made for pet foods and supplements, but keeping the rules described above in mind should help. If the pet owner has any questions, he or she should not hesitate to contact the manufacturer. Asking for advice from parties other than the manufacturer, such as FDA or state regulatory officials or university experts, may also be a good source of unbiased information. Also, as with other health matters, the pet's veterinarian should be consulted on dietary choices, especially with respect to any special use products.