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INTERPRETING PET FOOD LABELS -- PART 2: SPECIAL USE FOODS

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As detailed in Part 1 of this article which appeared in the November/December 1998 FDA Veterinarian, there are many regulations at both the Federal and State level governing the labeling of pet foods. With increasing health-consciousness with respect to diet, many Americans are now reading and scrutinizing food product labels more than ever. This task becomes cumbersome when the same efforts are applied to pet food labels. Since the rules for pet food and human food labels are different in many respects, attempting to translate the meaning of certain claims on pet food labels may be frustrating to some consumers. Therefore, knowledge of the unique rules for pet foods is needed for the consumer to understand labels more thoroughly and make the correct dietary choices for his or her pets.

Part 1 described many of the rules applicable to all pet foods. Most consumers offer their pets "complete and balanced" foods, and the previously described regulations cover these types of products. However, these rules do not necessarily cover all aspects of some foods intended for special uses. Part 2 discusses the additional or special requirements for the latter group of products.

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 (see Part 1). "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. If the pet owner is going to give his or her pet treats or biscuits more than only occasionally, or as a large proportion of the diet, it is best to feed a product that bears an AAFCO nutritional adequacy statement. In this way, the treat or biscuit would not disrupt the nutritional balance of the whole diet.

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. However, 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. For example, 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 of 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. To understand CVM's position on health-related claims on pet food labels, one must first examine the law upon which FDA regulations and policies are based.

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 distinction between food and drug is critical in terms of FDA's regulatory authority. A new drug, whether for humans or other animals, must be subject to an approval process prior to marketing. Adequate data from controlled scientific studies to demonstrate safety and efficacy for its intended use are required before a drug product may be approved. Unapproved drugs on the market are deemed adulterated drugs and may be subject to regulatory action. In contrast, the law does not require a food to be subject to a similar premarket approval process unless it is considered to be a food additive.

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." In effect, such a claim establishes 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. Therefore, 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.

The criteria for what constitutes a drug claim extend beyond the specific wording that a product will "treat" or "prevent" a disease. An implied drug claim can be any claim that suggests that use of the product will be of therapeutic benefit. Therefore, any discussion of a medical condition on a food label implies that the product

will affect that condition and could be a drug claim. Reference to a product as equivalent to a drug (for example, "the herbal alternative to cortisone") may also be a drug claim. In addition to text, symbols or other depictions that may imply medical benefit (EKG tracings, medical insignia) may be drug claims.

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. The aforementioned aside, FDA recognizes that there is an integral relationship between diet and disease. Congress also acknowledged this relationship in 1990, when it passed the Nutrition Labeling and Education Act (NLEA). Among other food labeling changes, the NLEA required the promulgation of regulations to allow for certain "health claims" on foods for human consumption. These are claims wherein discussion of intake of a certain food with the reduction of risk of a disease could appear on the label without automatically rendering the product a "drug." For example, the relationship of dietary fat, saturated fat and cholesterol intake with the reduction of risk of cardiovascular disease could appear on some foods low in these factors. Other relationships, such as calcium and osteoporosis, and salt and hypertension, are also mentioned in the NLEA.

A similar relationship between diet and disease can be argued for pet foods. The specific diet/disease relationships as spelled out in the NLEA would not necessarily apply to nonhuman animals. For example, the same "fat/heart disease" claim on a pet food would be misleading, since dogs and cats do not suffer the same incidence of atherosclerosis and myocardial infarct as do humans. Still, the principle could be the same. The NLEA did not expressly include animal feeds or pet foods in the new law, so it would be difficult to promulgate Federal regulations to allow for similar "health claims" on pet food labels at this time. CVM has incorporated some of the philosophy of the NLEA in its policies in order to allow for meaningful health-related information on pet food labels to reach the consumer without violating the intent of the law.

FLUTD Products

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). The exact causes of FLUTD are still unclear, and a number of dietary and non-dietary factors may be involved. With respect to dietary factors, the ability for a cat food to produce an appropriately acidic urine, and to a lesser degree, to limit the amount of dietary magnesium, may beneficially affect the incidence of the disease. Although FLUTD occurs in less than one percent of the cat population, it is of tremendous concern to cat owners. Thus, many veterinarians and cat owners look for these qualities in making choices about cat food products, and cat foods designed specifically to address this issue are on the market. 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 percent 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. The only exception to this last requirement is if a valid AAFCO calorie content statement is also on the label, wherein the calorie content is higher than would be estimated from the guarantees.

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. It must be noted that 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. Thus, it is not surprising that 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. Thus, until recently, there was no official definition for "lite" pet foods, and the term has been subject to misuse by some companies. Even if one manufacturer's "lite" product was lower in calories than its regular product, the caloric contents of products vary greatly between companies. Thus, one company's "lite" product could be higher in calories than another's regular product. Also, calorie content statements were only voluntary, and rarely appeared on pet food labels. These facts had made it difficult for the veterinary professional and pet owner to fully assess and compare the calorie content of various products.

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 percent 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.

Despite these new rules, a successful weight loss program takes owner involvement, too. Even a "lite" food can cause weight gain if fed to excess. Thus, 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 as dry skin, flaky skin, or itching may be drug claims.

Perhaps most notorious is the claim for a product to be "hypoallergenic." Elimination diets for the diagnosis and management of food allergies in pets have been on the market for years. 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. This new marketing

niche was detrimental in two respects. The true nature and incidence of food allergies was clearly overemphasized and misrepresented. Also, the novelty of lamb and rice was diminished, so the usefulness of these ingredients as elimination diets has markedly decreased.

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.

However, changes in the law have opened the door for the market for medical foods. The NLEA specifically exempts medical foods from meeting some of the nutrition labeling requirements as are mandated for other foods for human consumption. This creates a paradox, since a product could be exempt from fulfilling nutritional labeling requirements (including requirements for health claims) by meeting the category definition of a medical food. Strict labeling requirements should be more critical for foods intended for people with medical conditions. In response, FDA is considering new regulations under existing law for both foods and drugs to define a separate category for medical foods, and will likely incorporate a premarket approval process.

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." However, the original intent of this phrase was not for use on VMF labels. The phrase was taken from the AAFCO model pet food regulations and applied to labels for medicated pet foods. These are products that contain an antibiotic or other drug, and must undergo the same premarket approval process as required for other drugs. In contrast, VMF are regulated as foods and are not subject to the same controls as drugs.

As foods, VMF are subject to the same labeling requirements as are any other nonmedicated 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.

Despite label restrictions, companies often establish the intended use of their VMF products through brochures, advertisements, or other promotional materials. This usually provides ample evidence of the intent to offer the products as drugs. However, CVM recognizes that since there are scientifically sound bases for use of these products in some cases of disease in dogs and cats, these products do serve a purpose to veterinarians, their clients, and their patients. Also, veterinarians and their professional staff obviously must be informed of the indications, contraindications, and directions for use of the products. Thus, CVM generally exercises regulatory discretion with respect to distribution of truthful information on products and their use in disease to the veterinary professional.

The same information distributed to the pet owner, however, is of more concern. 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"

Nutritional supplements for pets have been available for many years. These are products that provide a source of a recognized essential nutrient, such as calcium or vitamin A, and are intended to augment and ensure nutritional completeness of the diet. Labeling for nutritional supplements must follow the same rules as for other pet foods. If it claims to be a vitamin or mineral supplement, the label must bear guarantees for each vitamin or mineral in the product.

Before the advent of regulations governing the nutritional adequacy of pet foods, owners could not be assured that the foods they were feeding were complete, so some supplementation for "insurance" might have been prudent. However, with the availability of today's "complete and balanced" products, nutritional supplements are needed only in very rare circumstances. In fact, 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. 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.

It must be noted that DSHEA only applies to human products, not pet products. Thus, some of the substances allowed for sale as human dietary supplements may not be legally permitted to be sold for animals. There is good reason for this, though. 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. It is well known that 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. However, due to the large number of products on the market, it is sometimes difficult for FDA and State regulatory officials to effectively police them all. Therefore, the consumer should eye with scrutiny any claims that a dietary supplement or nutraceutical is useful for the treatment or prevention of disease, or promises that it will "improve" a condition or make the pet "healthier." As with any supplement, the pet owner should discuss use of a product for a pet with his or her veterinarian first.

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.