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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2007–N–0442 – Opportunity for Public Input on Standards for Pet Food and Other Animal Feeds

The Pet Food Institute appreciates the opportunity to submit comments, in response to Docket No. FDA–2007–N–0442, on the development of federal regulations for pet food. The Pet Food Institute represents the manufacturers of 98% of the commercially produced pet food in the United States, a $16 billion domestic industry with an additional $1 billion in export sales. Our members must produce pet food in the U.S. as a condition of membership and may also manufacture in other countries and under other controls as well. U.S. pet food has long been recognized as the gold standard for pet food quality, nutrition and safety, notwithstanding the recalls of 2007 that were precipitated by a deliberate, fraudulent adulteration of food grade ingredients.

PFI members understand that the year 2007 was difficult for consumers as well as manufacturers of products because of several high profile recalls that occurred. In response to food-related issues involving spinach, seafood, peanut butter and pet food, Congress included provisions in the Food and Drug Administrative Amendments Act of 2007 establishing new requirements related to food safety. Specific to pet food, FDAAA requires the U.S. Food and Drug Administration to establish federal regulation for ingredient standards and definitions; processing standards; and updated standards for the labeling that include nutritional and ingredient information.

No industry was more affected by the events of late 2006 and early 2007 related to food safety than the pet food industry. The recalls that were announced in the spring of 2007 were the direct result of the deliberate addition of melamine to food ingredients that ultimately were used in the production of certain pet food products. It appears that the melamine was added to wheat gluten and wheat flour in China by the manufacturers of the ingredients for the purpose of artificially raising their protein content. Melamine is a substance that is not approved for use in food in the United States or China and never should have been added to the food ingredients by their Chinese manufacturers. As a result of the presence of melamine, and the related compounds that were carried by the melamine (hereafter

referred to as MARC), a number of pets in the U.S. developed renal failure.

Prior to the MARC recalls, normal laboratory processes would never have found the contaminant. When the first MARC recall was announced, no cause could be identified for the renal issues that had been reported. The concern of the industry and the regulatory community was so great that they banded together and conducted a year's worth of laboratory work in only three weeks by working around the clock to find the source of the problem.

In the Senate Hearing on the recall held on April 12, 2007, Dr. Stephen Sundlof, then Director of the Center for Veterinary Medicine and current Director of the Center for Food Safety and Applied Nutrition of FDA put the safety record of pet food into perspective when he said, "Pet food is generally, in fact traditionally has been, a very safe product. …This is quite disturbing in this case because this is so unusual and we're dealing with a substance we had never encountered before."

Unfortunately, no amount of additional regulation or monitoring would have prevented this deliberate act of adulteration, but as a result of the incident, industry and regulators alike have increased their level of vigilance.

Those involved in making and distributing pet food are dedicated to promoting the health and well-being of pet dog and cats. Great care is taken to ensure that no ingredient is used that might cause harm or would not be useful in promoting pet health. The MARC recalls struck deep at the core of the pet food industry.

Because of the complicated set of state and federal statutes and regulations that have evolved over time, some consumers do not understand the full scope of the ways in which pet food is regulated. In the U.S., pet food is among the most highly regulated food products. The model state laws and regulations that apply to pet food and were adopted by most states were developed by the Association of American Feed Control Officials (AAFCO), the association of state regulators who regulate animal feed and pet food. FDA actively participates in the deliberations and proceedings of AAFCO – along with officials from the U.S. Department of Agriculture and the Environmental Protection Agency – to develop model statutes and model regulations that are adopted by the states. These models cover ingredient definitions and labeling for the animal feed sector, which includes pet food, and provide a comprehensive framework for the regulation of pet foods in the United States and around the world. The AAFCO models have been developed over many years of discussion and practical usage and therefore provide the building blocks to enable FDA to meet the legislative charge mandated by FDAAA.

For instance, as a part of existing state feed laws designed for public protection, detailed labeling requirements are already in place. Those same laws also define the ingredients that make up animal feed. In contrast, few ingredients used in human food have the same requirement that they be expressly defined. The definitions developed by AAFCO are used throughout the world because trade in animal feed, both domestically and globally, is dependent on consistent language and meaning.

As FDA moves forward with developing federal regulations for pet food, a fact that must not be overlooked is that under existing FDA requirements, each pet food company currently has the responsibility for producing a safe product. For that reason, companies have developed specific processing parameters so that consistent, safe products are produced.

The FDA Center for Veterinary Medicine has a program under development that significantly preceded enactment of FDAAA and appears that it could fulfill many of the requirements of FDAAA without much adaptation. This program, the Animal Feed Safety System (AFSS), should be brought to fruition prior to the expenditure of additional agency resources to create what would be duplicative regulations. It would be a significant loss of previous effort not to use the work that has already been completed on AFSS that may be applicable to meeting the mandate of FDAAA.

One area not specifically addressed by AFSS is consumer education, a matter of primary importance to PFI and to FDA. FDA's efforts in this area should continue along with support from the states. PFI will continue to assist with efforts to educate both consumers and regulators about our industry whereby our members manufacture food for pets that promotes and maintains long healthy lives. This fact is acknowledged by consumers as evidenced by historic trends, as well as the latest data, of the American Customer Satisfaction Index (ACSI).

The latest nationwide survey by ACSI shows purchasers of pet food products have a satisfaction index of 83%, tied with that of soft drinks and second only to that of personal health and cleaning products. The ACSI is an economic indicator, calculated by the National Quality Research Center (NQRC) at the University of Michigan, that measures the satisfaction of consumers across the U.S. economy. NQRC interviews about 80,000 Americans annually about their satisfaction with the goods and services they consume. Results from data collection and analysis are released to the public each quarter and are used by academic researchers, corporations and government agencies, consumer organizations and others. The ACSI figures validate that pet food is a widely accepted product with a history of safe use and strong consumer acceptance.

A final matter that FDA should consider is that the regulations for pet food developed as mandated by FDAAA may conflict with existing state and territory statutes. This conflict must be addressed prior to the implementation of any federal regulation lest pet food companies be required to meet divergent federal and state requirements. Federal regulation could reduce the disparity between states in their application of the long-standing AAFCO Model Bill and Regulations.

As previously described, the long history in the development and usage of AAFCO model regulation has been effective in providing a framework for consumer protection. Making significant changes to existing pet food regulations would not provide more clarity in pet food labeling standards, ingredient definitions or processing requirements, but would very likely result in a situation whereby the consistency of regulations that have been developed could devolve into a mishmash of conflicting requirements. This would not be helpful to consumers who want to remain confident in the pet food they purchase, or to manufacturers of pet food who must try to meet these requirements.

Labeling

The Federal Food, Drug, and Cosmetic Act was enacted to ensure that all foods, human and animal, are safe and labeled with mandatory information that informs consumers of material information needed to make informed purchasing decisions. FDA has long-maintained such requirements at the federal level and they are uniformly followed throughout the pet food industry.

The task of ensuring that these requirements remain current and effective is shared with the Association of American Feed Control Officials (AAFCO). AAFCO has developed Model Regulations for Pet Food and Specialty Pet Food that include specific provisions for product labeling. These regulations have been adopted by the majority of the states and provide a framework for the development of federal labeling regulations for pet food under the Food and Drug Administrative Amendments Act (FDAAA).

Under the AAFCO model, pet food labels provide consumers with a guarantee of nutritional content which is much more specific than requirements for human food products. Labels are specifically tailored to the role of pet food in companion animal diets, thereby ensuring that consumers have complete and reliable information. Failure to abide by these requirements renders the food "misbranded" and it is, of course, unlawful to engage in such practices.

As shown in Table 1, the mandated elements on pet food labels – which were developed by AAFCO – already provide consumers with specific information on what to feed, how often to feed, how to feed as well as what is in the product. Some labels, where space permits, may provide additional information about the product or regarding general pet care. This supplemental information provides companies the opportunity to convey innovative product benefits and to essentially "compete" on the basis of adding value to the mandatory federal and state requirements that all pet foods must satisfy. This information too is subject to strict federal and state laws that prohibit any labeling information that is false or misleading.

Table 1

Mandated elements	**AAFCO Pet Food**	**AAFCO Feed**	**FDA Human Food**
Product name/brand name	**X**	**X**	**X**
Intended species	**X**	**X**	
Net content	**X**	**X**	**X**
Guaranteed analysis	**X**	**X**	Nutrition Facts Box (typical values only)
Ingredient listing	**X** No collective terms allowed	**X** Allows collective terms	**X** Allows "may contain" statements
Nutritional adequacy statement	**X**	Animal Class	
Feeding directions	**X**	**X**	Serving Size Only
Distributor/manufacturer	**X**	**X**	**X**

Pet food labels clearly provide much more information than that found on any other food item sold to consumers. While some have been vocal about the perceived "ambiguity" of pet food labeling, pet food labels clearly provide a great deal of information. Any confusion or perceived ambiguity that may exist about pet food labels is likely a result of a lack of understanding of the full extent of the labeling regulations and the application of those regulations. In understanding these concerns, and addressing the underlying goal of ensuring effective labeling, it is important to distinguish the utility of the label information from the underlying regulations.

While this is of some concern, a lack of understandability to the consumer does not mean that the regulations fail to produce accurate and complete labeling information for that consumer.

As an example, the labeling of pet food product names must follow specific regulations for naming conventions that ensure uniformity in how products are described and names that reasonably capture the nature and quality of the characterizing components of the pet food.

These requirements may, to the casual observer, seem overly complex even though the regulations are strictly constructed to provide content information to regulators as well as the public. Human food rarely bears such constraints. Moreover, the vast variety of pet food product sizes poses tremendous challenges for including all of the required elements while making an attractive, informative and readable label.

Across the food industry, companies employ regulatory affairs experts whose job it is to understand and apply labeling rules that are often highly prescriptive. The detailed regulations, while perhaps not readily understood by the consumer, are written in a fashion that ensures that consumers receive uniform, useful information on the pet food label. A goal of the planned review is to ensure that these regulations produce a label that fully serves consumers and their pets.

Beyond ensuring that consumers have the ability to utilize complete and accurate labeling information from which to make informed decisions, there is value in ensuring that those interested in a better understanding of the underlying rules have the ability to do so. The pet food industry, via labels, Web sites and other communication vehicles, views education of consumers as vital to the shared goal of providing consumers healthful, nutritionally complete, high quality pet food options. FDA has developed educational documents describing pet food labeling and has been criticized for the length and detail of those documents. Better communication about the underlying pet food labeling rules provides a value to consumers in light of the complex labeling requirements that are illustrated in Table 1.

Feeding a pet a complete and balanced pet food is different from the experience that people have in consuming a nutritionally balanced and sufficient diet for themselves. People are encouraged to create a balanced diet for themselves from a variety of food choices and are used to hearing about food pyramids. With respect to pet food, most products are nutritionally complete and balanced, meaning that the single product provides all of the nutrients needed by the pet. Few of such products exist for human consumption, with the exception of products that are for limited use like infant formula and Ensure®. Pet food manufacturers have taken on the responsibility of making nutritionally complete and balanced diets for pets based on years of science-based nutritional research to support long healthy lives for pets.

FDA has announced that it will be conducting consumer research on labeling later this year. PFI applauds this next step. All would agree that important regulatory issues that turn on consumer protection benefit from objective information about consumer perception and understanding. The existing regulatory framework produces labels that have proven very useful to consumers. At the same time, as has long been the case, the constant review and revisions to the labeling rules when necessary is an important process that is best supported by empirical data as one valuable tool. Once this research has been concluded, FDA should make the results available to stakeholders for consultation and review prior to rulemaking. PFI looks forward to providing comments on the design of the research in response to Docket No. FDA-2008-N-0249.

Finally, the AAFCO model labeling regulations and guidelines provide a framework for the establishment of federal labeling requirements. FDA should keep in mind the differences

between human food products and pet food products when the federal regulations are developed and should continue to involve stakeholders in the development process.

1. How could the nutritional information (e.g., guaranteed analysis, nutritional adequacy statements/lifestage claims) already present on pet food labels be improved?

As illustrated in Table 1, pet food labels currently are required by state and federal regulations to provide a wide variety of nutrition information beyond what is mandated for other animal feeds or human food. Most pet food companies provide even more information voluntarily, which may include helpful pet care information and guarantees in addition to those required by the AAFCO model regulations and state laws (crude protein, crude fat, crude fiber, moisture). However AAFCO allows only certain additional voluntary guarantees of nutrient content that it views as important to consumers. Expanding the list of allowed voluntary guarantees could enable pet food companies to provide additional information that would be of interest to consumers. Within the bounds of truthful, non-misleading information, regulatory flexibility is vital to fostering innovation and competition that best serves consumers. PFI cautions that an effort to highly regulate and standardize all information that appears on the label will undermine the shared goals of accurate labeling of innovative, useful pet foods that reflect the best science relating to the diet of companion animals.

In issues raised before AAFCO and in other public comments submitted on FDAAA, some have suggested that additional information be provided on pet food labels. For instance, some consumers may wish to see carbohydrate guarantees on pet food labels. Although not currently permitted, AAFCO has been working to define carbohydrate-related terms and labeling standards. Permitting the voluntary placement of this information on labels could help respond to consumer requests.

Also in comments to AAFCO and on FDAAA, some have suggested that all pet food products be required to list caloric content. Many companies already provide this information on product labels on a voluntary basis as allowed by AAFCO following a long-standing request by the industry to be able, in some cases, to show calorie content. Requiring detailed caloric information on all pet food labels could create consumer confusion because all calories are not equal. There are highly digestible calories and calories with lower digestibility. A consumer or even a veterinarian could easily be misled into believing that one diet with 3500kcal is equal to any other with 3500kcal, when the science shows that is not true. A simple example would be to compare an 800 calorie ice cream sundae with an 800 calorie steak or an 800 calorie salad. Obviously each of those would provide different levels of nutrition. Again, the value of such information must carefully be considered relative to whether the presence of information informs consumers or whether mandating such information actually may create confusion where none now exists.

When it comes to pet food, people would be even less understanding of the significance of calorie information on the label than they are about the impact of such information on human food. This issue would be magnified for dog owners, because of the great diversity in the size of dogs. As a result, numerous problems could result from calories being required on pet food labels:

- Pet owners could base their purchasing decisions solely on the caloric content, even though they do not necessarily understand the significance of that content

- Pet owners could base their purchasing decisions solely on the caloric content, even though they do not necessarily understand the nutritional composition or digestibility of the product
- Pet owners could ignore the feeding instructions and feed their pet based solely on the caloric content, potentially creating health problems for their pet
- Pet owners could be confused by the ways in which caloric information is presented (e.g., 500 calories per 8 ounce volume and 250 calories per half cup, which would be equivalent in terms of calories by volume).

Further, when calculating caloric values, protein and NFEs (Nitrogen Free Extract, a.k.a., carbohydrate) all share the same value of 4 kcal per gram. Comparing a high protein diet to a high carbohydrate diet with the same number of calories tells a completely different story from a nutritional perspective than what one might expect, such as comparing an Atkins™ diet with a NutriSystems™ diet for humans.

Maintaining optimal weight over the life of an animal is vital to good health. Many member companies have devoted substantial efforts to understanding and communicating this information to consumers through expanded feeding instructions, body weight evaluation and other supplemental information.

It is recognized that some consumers will always want more information than others, a reality complicated by the fact that consumers will disagree as to what added information they view as most valuable. FDA effectively meets its statutory consumer protection and animal health obligations when it ensures that necessary information appears on the pet food labels. This information enables consumers to make informed purchasing decisions. The charge that the industry bears is to meet the federal and state statutory requirements while producing a product that has a label that is informative and appealing to the consumer. Additionally, while the statement may seem obvious, the label must be readable.

All pet food labels comply with mandatory requirements that ensure that the underlying regulatory goals entrusted to FDA are met. The constraint of the available space on the label points to the value of considering greater flexibility in how information is presented on smaller size labels. While not allowed by current pet food regulations, a potential solution may be size-relative labeling accommodations as allowed on chewing gum and other confections. Providing more information on a label does not always result in a more informative or readable label for consumers, while providing educational support on the package may be useful. In every instance, stakeholders, and ultimately regulators, should fully consider what is the minimum mandatory information that should appear on the pet food label. As noted above, the current requirements provide a great deal of information to consumers.

The AAFCO Pet Food Committee, which includes an FDA representative, continually evaluates labeling requirements and provides a forum to discuss pet food nutritional and content labeling. AAFCO has launched a review of its nutritional adequacy substantiation requirements that will evaluate recommendations made by the 2006 National Research Council publication on dogs and cats. This review should be completed and incorporated into the current AAFCO nutritional adequacy substantiation requirements to be sure that they are as up to date as possible before any additional nutrition labeling requirements are mandated on pet food companies.

One final matter that should be considered with respect to nutritional information on pet food labels is the understanding of all the label components. FDA, state regulators and the industry should continue to educate consumers on label components, why specific information is required and why certain language must be used.

2. How could the ingredient information already present on pet food labels (i.e., the ingredient list) be improved?

For any pet food ingredient that is defined by AAFCO and listed in the AAFCO Official Publication, regulations require that manufacturers use exactly the same ingredient name on their labels. Some current ingredient names required by AAFCO are unknown or unfamiliar to consumers and may create confusion or alarm. Some ingredients, such as vitamins and minerals, must be designated by their chemical source. For example, Vitamin B-6 is currently required to be listed as pyridoxine hydrochloride. Brewers Rice (small fragments of rice kernels that have been separated from the larger kernels of milled rice) is another commonly used ingredient in pet food that is not understood by many consumers, who often mistakenly believe it has been used in the brewing of beer. FDA should engage appropriate stakeholders who are familiar with pet food ingredients on the use of common and usual names for ingredients prior to rulemaking. The legal principles that dictate naming based on AAFCO definitions, common industry practice, consumer understanding and descriptive terms has generally served consumers well. An educational goal of the agency should be improved consumer understanding of the ingredients used in pet food.

Further, unlike other animal feed labeling and some human food labeling, pet food labeling cannot utilize collective terms which aggregate a group of similar ingredients. These are terms such as “animal protein products”, “forage products”, grain products”, and “plant protein products”. Pet foods must list the specific ingredient such as “corn”, “vegetable oil” and “calcium carbonate”. Conversely, even human foods can use some collective terms, such as the statement “May contain the following (soybean oil, canola oil, corn oil)”.

Although ingredients currently must be listed in order of predominance on the Ingredient Statement, some have suggested in comments on the FDAAA that the exact percentage for each ingredient be a labeling requirement. This suggestion causes extreme concern for the pet food industry. Pet food formulas are highly confidential and represent the collective investment of years of nutrition and processing research. Formulas are the “Crown Jewels” of a pet food company and are proprietary trade secrets, which are protected under federal law (18 U.S.C § 1831-1839). Requiring the revelation of exact percentages for ingredients, would be equivalent to requiring that Coca Cola reveal its trade secret formula. All food companies, including pet food companies, need to be able to compete in the marketplace without the requirement that they divulge their intellectual property. Furthermore, there is no compelling argument on how this type of information would benefit consumers regarding the nutritional completeness or appropriateness of the pet foods they choose to feed.

Also on the matter of labeling by actual percentage, because of natural variations in ingredient nutrient content due to seasonal, geographical, climatic and genetic diversity, slight adjustments may be made to the recipe in order to meet the nutritional requirements of the pet. In the event that ingredient percentages were required on labels, these slight variations might cause a product to no longer meet the implied guarantee of the stated percentage even though the ingredients would still be listed in the correct order by weight. The changes to labels that would be required would precipitate even more confusion because there could conceivably be several different labels on the market at one time. Furthermore, it is uncertain how this type of information would benefit consumers regarding the nutritional completeness or appropriateness of the pet foods they choose to feed. The value and desirability of ingredients is often not solely a function of percentage of inclusion. Hence, requiring percentage labeling invites a basis for evaluation and comparison that may be entirely subjective and irrelevant to the nutritional

content of the pet food. Further, consumers may not recognize that there are indeed differences between, for instance, “soybeans”, “soybean meal” and “soybean oil”, leading to the misconception of ingredient “splitting”. Indeed, these are discrete and individual ingredients included in formulas for very different nutritional and functional effects.

3. How could the current feeding instructions/recommendations section already present on pet food labels be improved?

Current feeding guidelines for “complete and balanced” pet foods are required, at a minimum, to advise consumers of the amount of pet food to feed per body weight along with the frequency of feeding. Feeding guidelines are required to be consistent with the intended purposes of the foods, such as whether the product is designed for feeding to kittens/puppies or adult pets. Instructions for all intended purposes must be included on the label.

Current feeding instructions provide consumers with a useful initial guide for the amount of food to feed a pet. However, these feeding instructions reflect the reality that there is great diversity between individual pets, particularly among dogs which may range in size from a 6 pound Chihuahua to a 200 pound mastiff.

Feeding instructions are designed to provide consumers with the flexibility to determine the appropriate feeding amount for their individual pet by providing a range of food to be fed by volume based upon the weight of the animal. Yet because of the diversity among pets (age, activity level, genetics, temperament, etc.), it may be necessary for pet owners to adjust the amount fed based upon the body condition of the individual animal. Such an adjustment is implicit in the instructions provided on the label.

Current feeding instructions take into account several factors when they are developed, including: caloric content of the food, bulk density (weight to volume ratio) of the food and the estimated energy requirement of the animal. Pet food products are precisely formulated based upon a specific nutritional philosophy and are tailored for specific life stages. The caloric content of the food is achieved based upon the nutritional philosophy of the responsible pet food company, and the feeding instructions reflect the collective knowledge on energy requirement of the animal and the caloric content of the food. An example of divergent nutritional philosophies for human food products can be found in the numerous weight loss programs on the market: Weight Watchers™, Atkins™, Jenny Craig™, South Beach™, Zone™, etc. All of these programs approach weight loss from a different nutritional philosophy, and the program that may be more effective for one person maybe less effective for another.

How pet food companies get to this important end-point is varied and reflects innovation that benefits pets. A highly proscriptive approach beyond the current regulations, while ostensibly promoting more information to consumers, may in fact impede innovation and force a “cookie-cutter” approach to product formulation what will not serve either consumers or their pets well.

4. Should feeding recommendations be required on the labels for all types of pet food?

Under current AAFCO regulations, feeding recommendations are already required for all “complete and balanced” pet food and “complete and balanced” treats for all intended uses indicated in the nutritional adequacy statement. Those pet foods or treats which are not

"complete and balanced" are not required to have specific feeding directions because they are not intended to supply complete nutrition.

Under current AAFCO regulations, a nutritional adequacy statement is required for all pet foods and pet treats clearly indicating whether the product is either:

- Nutritionally complete (for any or all life stages); or
- A "snack," "treat," or "supplement;" or
- Intended for intermittent or supplemental feeding only.

For those therapeutic diets that are sold under the guidance and prescription of a veterinarian, the only feeding direction that may be provided is "use only as directed by your veterinarian." In those instances the veterinarian will direct the pet owner on the amount of food to feed the animal.

Pet chews made of animal skin, hide, wood or man-made materials as well as hooves, ears, animal bones and ligaments are not considered to be pet foods and are exempt from this requirement unless the label of the product shows that it contains nutritive value by listing values for protein, fat, etc.

5(a). Should a Nutrition Facts box, similar to the format that appears on human food labels, replace the current Guaranteed Analysis that currently appears on pet food labels?

Currently pet food manufacturers are required to list a guaranteed analysis for specific nutrients (crude protein, crude fat, crude fiber, moisture and any voluntary guarantees) and provide a statement of nutritional adequacy on product labels. This information states the appropriate nutritional use of the product (e.g., whether it is "complete and balanced" or "for intermittent or supplemental feeding"). This statement is reflected in feeding recommendations for the appropriate life stage. Collectively this information provides an overall picture of the nutritional use of the product, unlike a Nutrition Facts Panel on human foods. Thus, the differences between the information on pet food and human food labels reflect the very different roles that the food plays in the diet of the pet versus the diet of its owner.

The Nutrition Facts Panel on human foods shows the approximate size of a single serving of the food and presents the amounts of selected nutrients typically present in one serving. For most nutrients, the amount is also presented as a percentage of the established daily value for that nutrient. Consumers can determine how much of the displayed nutrients they are getting each day by adding up the amounts shown for all of the foods they consume.

Because of the concerns that the U.S. diet was too high in some nutrients and potentially not high enough in others, a small subset of all nutrients were selected by an expert nutrition panel to be mandatory declarations in the Nutrition Facts Panel on human foods. That's why declaration of typical amounts of total calories, calories from fat, total fat, cholesterol, sodium and fiber are all mandatory, but most other essential nutrients are voluntary declarations.

The current Nutrition Facts Panel on human foods is intended to provide information to consumers so they can make educated choices about the food they eat, with the goal of promoting healthy lifestyles. Presumably the suggestion to use such an approach on pet food is intended to give consumers information to make healthier food choices for their animals as well. Yet this suggestion ignores several facts particular to companion animal nutrition and the

nutritional composition of pet food products that obviate the need for a Nutrition Facts Panel on pet food as required on human food.

First, most pet foods are 100% nutritionally complete. The significance is that consumers do not need to assemble a nutritionally complete diet for their pet from a series of individual food items as they must do for themselves. However, consumers may choose to add treats or snacks for the pet, which may complicate the nutritional intake.

Second, the large variation in the body weights of mature cats and dogs, ranging from 6 pounds to 200 pounds, precludes the establishment of a standard serving size. It is for this reason that pet food labels include feeding instructions recommending feeding amounts based upon the nutritive content of the food and weight ranges of animals to which the food might be fed. In contrast, the Nutrition Facts Panel on human food contains information based upon a single standard serving size as determined by the food maker.

Third, the variation in body size also makes it impossible to establish Daily Values for nutrient intake for individual dogs or cats, so there cannot be a "% DV" value presented on a pet food label. For instance, a value that would be completely appropriate for an 80-pound dog would be quite inappropriate for a dog that weighed 30 pounds.

Finally, no consensus exists among experts as to exactly which of the approximately 40 essential nutrients for dogs or cats should be of special concern. Without a short list of critical nutrients to feature on a label, a Nutrition Facts panel on pet foods would have to be large enough to accommodate information about all essential nutrients. Such a panel would be difficult if not impossible to fit on most labels and could also be difficult for consumers to understand or interpret. The panel would be quite large and would not be compatible with most pet food package sizes, particularly wet products which are sold in packages as small as 3 ounce cans. However, at the same time, there is a consensus around what constitutes a nutritionally complete pet food, and this concept is already captured by the current mandatory requirements.

The very effectiveness of the Nutrition Facts Panel required on human food is uncertain. Dr. Lester Crawford, while serving as Acting Commissioner of FDA, reported on June 3, 2004 in testimony to the House Committee on Government Reform on the findings of the FDA Obesity Working Group that "Since passage of the NLEA more than 10 years ago, consumers have had nutrition labeling on most packaged foods. A recent report from FDA's CFSAN indicates that consumers both like and use the Nutrition Facts panel and the health and nutrient content claims. However, it is not clear how successful consumers have been at using labels to eat healthier diets."

It is for these reasons that a Nutrition Facts Panel that mimics what is required on human food labels is inappropriate for pet food.

5(b). If so, how could this Nutrition Facts box be made to clearly distinguish it from human food labeling?

As stated in the answer to question 5(a), a Pet Food Nutrition Facts Panel in the style of the Nutrition Facts panel on human foods would not be appropriate for pet foods. The nutritional needs of pets are well understood and the current labeling rules are well-framed to reflect those very specific nutritional needs.

6. What other information should be required on pet food labels that is not generally present on pet food products sold in the United States?

Pet food labels in the U.S.A. are already very complete and, as outlined in Table 1, are required to contain more detailed information than human foods and other animal feed. U.S. pet food labels generally contain more information than required in other countries as well. Pet food labels are adequate to help consumers make educated choices about which food to feed their pets.

In public comments submitted on FDAAA some have suggested that grades of ingredients should be indicated on the label or that the use of food-grade (a.k.a., "human grade" or "edible") ingredients or food-grade claims would be helpful to consumers. These statements not only violate AAFCO and state regulations with regard to a prohibition on the expression of grade or quality, but may actually be misleading. If edible standards are not maintained throughout the entire manufacturing process, then neither the ingredient nor the final product is edible or food-grade. In the United States, there is no such official designation as "human grade."

While pets have sensory perception that influences taste preference, this complex area is not accurately or simply addressed merely by imposing artificial notions of "human grade." Rather, the current regulatory framework achieves its essential purpose—everything that goes into the pet food package is safe and suitable for animal consumption.

As earlier stated, providing additional information about the reasons that certain ingredients are included in a food may be of interest to consumers and may not be not currently allowed on pet food labels. An opportunity to provide that information would be appreciated by both consumers and the industry.

7. Are there existing state laws, regulations, guidelines, or other models that FDA should consider when drafting the proposed pet food labeling?

The Official Publication of AAFCO provides comprehensive model regulations on pet food labeling, nutritional composition and ingredients that have been developed over many years of discussion and practical usage. These models are intended to promote uniformity between states for the enforcement of feed safety and labeling laws.

Individual states have long-standing feed laws designed for consumer protection, and many states have adopted the AAFCO models. For those states that have not adopted the AAFCO models, the enforcement of those models by other states has created de facto nationwide pet food regulation in the U.S. The AAFCO models also have been used internationally in the development of regulations for pet foods.

Any new regulation that is imposed at the federal level must take into account the requirements that already exist in virtually all state laws for the inclusion of crude protein, crude fat and crude fiber on all feed labels. A federal regulation that preempts that language may be difficult for state regulators to enforce.

In addition to the AAFCO models, the Federal Food, Drug, and Cosmetics Act applies to all food, whether it be for people and other animals. The regulations promulgated under Federal Food, Drugs and Cosmetics Act apply to pet food as specified in the Code of Federal Regulation. FDA should continue to work cooperatively with AAFCO to sustain the remarkable success in maintaining a comprehensive, uniform approach to food labeling that brings all stakeholders into the process as issues arise at FDA and AAFCO.

Ingredients

Pet food products already are required to follow specific ingredient definitions in their products as developed by the Association of American Feed Control Officials (AAFCO). The AAFCO ingredient definition process, in which FDA is actively involved, has already developed a comprehensive set of globally accepted definitions for ingredients used in animal feed, which includes pet food. FDA accepts these definitions and the ingredient definition process under a Memorandum of Understanding (MOU) with AAFCO signed in 2007.

FDA should model its ingredient definitions after those developed by AAFCO in recognition of the MOU. If FDA is going to redefine existing feed definitions, then FDA should seek further input from those who are familiar with pet food ingredients, such as suppliers and manufacturers, as well as representatives of the larger animal feed business.

Given that pet food is a type of animal feed, many of the same ingredients that are used to make other animal feed are used in pet food as well. In addition pet food also uses materials generally intended for human food. Standards for pet food ingredients more specific than those that currently exist would be unworkable in the larger animal feed business. Many feed ingredients – other than those basic items known by their common and usual names (e.g. corn or wheat) – are specifically defined by AAFCO. If an ingredient definition is listed in the AAFCO Official Publication, pet food companies currently are required to use the relevant ingredient name in their list of ingredients.

While the AAFCO ingredient definition process serves an important role, there are opportunities to improve the efficiency of the process, which include and are not limited to providing dedicated FDA resources to assist with timely acceptance of new ingredients.

There currently exists a process whereby companies can seek approval for new food ingredients or new uses for existing ingredients that is known as self-affirmed GRAS (Generally Recognized As Safe) as allowed by FDA's notification rule. The self-affirmed GRAS process is available for all food ingredients regardless of whether they will be consumed by human or animals (62FR18938). This process is currently a successful program in use within FDA/CFSAN for human food, yet the process is largely unavailable for animal feed ingredients. FDA/CVM should implement the process immediately, and states should recognize that process, for achieving self-affirmed GRAS status for all new food/feed ingredients and ingredient uses.

On a related issue, for clarity and uniformity of action, FDA should make public its non-proprietary notifications on regulatory decisions. Making these decisions public would increase efficiency because regional FDA offices and states would not have to address questions of safe use for the same ingredients on several different occasions. Public decisions on these determinations also would benefit the public with a more transparent process and would assist industry because other companies would be aware of FDA's determinations

Finally it should be understood that regulatory ingredient definitions provide only the baseline for the actual ingredients used in animal feed. Individual manufacturers build their own ingredient specifications that may be more detailed and more restrictive than the basic regulatory definition. For instance, since pets are much more sensitive to mycotoxins than people, the specifications for grains used in pet food are more detailed and are much stricter in regard to the levels of mycotoxins that may be present in grain-based ingredients than for human food.

1(a). What kind of ingredient definitions would provide adequate information to ensure the safe and suitable use of the ingredients in pet foods?

AAFCO already has a comprehensive set of definitions for animal and pet food ingredients that have been developed over many years of discussion and practical usage. FDA should model its ingredient definitions after those developed by AAFCO for uniformity. Ingredient definitions are specific in their intended use including with respect to the target species when appropriate.

Safety does guide the current AAFCO ingredient definition process. FDA currently has oversight authority and actively reviews ingredient definitions for safety for the intended use within the AAFCO ingredient definition process.

Definitions should help to assure safety but should not be so restrictive as to exclude the use of safe ingredients. When a feed ingredient is considered for a new use, its broadest applications should be considered so that safe ingredients are not unnecessarily restricted to limited uses or limited species.

It must not be overlooked that the 2007 pet food recalls involved the deliberate adulteration of food grade ingredients with a substance not approved for use in any food for humans or animals: melamine. The melamine contained other related compounds (MARC) which caused the biological reaction in pets that resulted in renal failure. The 2007 pet food recalls that were prompted by the presence of this adulterant were in no way related to the definition of the ingredients. The excellent track record of ingredient safety demonstrates that the existing framework for how ingredients are evaluated and allowed for use is effective.

1(b). Should ingredient definitions also be developed for other animal feeds in addition to pet food?

Regardless of the limited interpretation made by some individuals, the Food and Drug Administration Authorization Act clearly applies to all food, not just pet food. Only Section 1002, “Ensuring the Safety of Pet Food”, is specific to pet food. As stated in the Federal Register Notice to which these comments are a response, new regulatory requirements, “if limited to pet food only, would be impractical to implement, difficult to enforce, and would not effectively provide the safety enhancements intended by the FDAAA.”

Ingredient definitions already exist for all animal feeds, which includes pet food, as described in the answer to ingredient question 1(a). If new definitions were limited to pet food, again quoting from the Federal Register Notice, those definitions “would fail to address the broader food safety concerns associated with food intended for other animal species, particularly food-producing animals” which would have further human food safety implications.

Ingredient definitions should be adopted that can work across all species because pet food ingredients originate from the same sources as those used for humans and other animals. There is no effective way to sort the meat or grains or any of the other ingredients used in these end-points at the time of growing, processing or distribution. As already stated, even some food grade ingredients may not be appropriate for pet food, while others may be. A train load of corn may be distributed into four separate areas of food use, human food, food-animal food, pet food or specialty pet food, with a fifth possible end-point being energy production. All of these end-points need to be able to speak in a uniform manner about what the name of the product really is, and to be able to describe it in a "defined" manner.

The current definitions allow for trade of ingredients and finished products in both domestic and international markets. Changing such definitions will have a detrimental effect on trade and will result in further confusion in the marketplace.

2(a). Should formal standards be a part of ingredient definitions?

Ingredient definitions should include standards when appropriate and applicable. This approach has been taken with some AAFCO definitions where standards have been incorporated as part of the definition as applicable. For example, the current AAFCO definition for Dried Chicory Root specifies the minimum amount of inulin to be present and the AAFCO definition for Meat Meal addresses the allowable level of calcium relative to the level of phosphorous.

2(b). If so, what information should be considered to establish a standard?

Standards should be risk-based and specified as appropriate. Standards should be developed in consideration of those parameters already listed in the AAFCO Official Publication under the "New and Modified Ingredient Definitions: A Guide."

2(c). Should such standards be developed for ingredients intended for other animal feeds in addition to pet food?

Ingredient definitions, which include standards as appropriate and applicable, already exist as described in the answers to ingredient questions 2(a) and 2(b). Any development of new or review of existing standards should continue to include ingredients for all animal feed, including pet food, because the sources of food and feed ingredients are so well integrated.

Processing

It is the responsibility and legal requirement of all food manufacturers to produce a safe product for the purpose for which it is intended. Intent should always be considered, as some foods, such as chocolate, are harmful to some species while completely safe for others. Pet food manufacturers certainly fall under this requirement and must comply with the Federal Food, Drug and Cosmetics Act. Requirements designed to ensure the production of safe products include standards set for Low Acid Canned Foods (21CFR 113), which apply equally to food for humans and animals. As stated on March 30, 2007, by Dr. Stephen Sundlof, then head of the FDA Center for Veterinary Medicine, "The pet food industry is subject to the same regulation as

the human food industry. We have the regulatory authority to take whatever protective actions are needed."

Would standards based on a riskbased, preventive, and comprehensive feed control measures approach, such as the approach described as an element of FDA's AFSS initiative, adequately address the processing standards requirement of section 1002(a) of FDAAA?

A risk-based program is always more appropriate as a regulatory tool than a rigid rule that has no scientific basis or that lacks sufficient flexibility as to provide an effective regulatory tool across the entire industry. FDA's Animal Feed Safety System (AFSS) takes a risk-based, preventative and comprehensive feed control measures approach that would be appropriate for the manufacture of all animal feed, including pet food.

As stated previously, it is the responsibility of all food manufacturers to produce safe food. Exactly what processes are used to achieve safety is part of the intellectual property of the manufacturer. This is particularly true for pet food manufacturers, who have well developed formulas and proprietary processes based on years of research. Rather than requiring highly specific standards for processes or for individual process steps, it is more appropriate to establish principles to follow during the procurement, processing and distribution of pet foods. As an example, within the standards set for Low Acid Canned Foods (21CFR 113) there is an allowance for variation between processes.

A wide variety of pet food products are produced – while new processes are continually invented, modified, and updated – to safely meet the needs of animals, as well as ever-changing consumer demands. A risk-based program assures the safety of finished products while preserving the ability of individual companies to innovate.

Ultimately it is the safety of the final product that is relevant, not the process by which individual companies produce that safe product. Thorough and adequate quality and safety checks are in place to protect the health of the intended consumer of pet food.

If so, what aspects of procurement, processing and distribution should be included in such an approach?

The approach should incorporate provisions only for those aspects of procurement, processing and distribution that affect the safety of the food. Detailed risk-based provisions should be developed in consultation with appropriate stakeholders who are familiar with pet food ingredients, manufacturing and distribution. Each manufacturer is responsible for the production of safe products and should have checks and balances in place to do so.

Should such standards be developed and applied to all animal feeds rather than be limited to pet food?

FDA's concern is expressed in the April 21, 2008, Federal Register notice on standards for pet food and other animal feeds that "certain new requirements, if limited to pet food only, would be impractical to implement, difficult to enforce, and would not effectively provide the safety enhancements intended by FDAAA." The provisions should be uniformly applied across all

animal feed. This will minimize confusion for producers of ingredients and for manufacturers that may produce both pet food and animal feed in the same facility.

Conclusion

Thank you again for the opportunity to comment on the development of FDA regulations for pet food. To further clarify our position on structure function claims, please see the attached document supplied to FDA/CVM in 2005. We look forward to the opportunity to contribute further to this process as it progresses over the coming months.

Sincerely,

Nancy K. Cook
Vice President

Attachment

cc: Dr. Bernadette Dunham
Dr. Daniel G. McChesney
Dr. Sharon Benz
Dr. William Burkholder

Submitted in conjunction with Docket No. FDA-2007-N-0442, June 13, 2008

Pet Food Institute
June 9, 2005

The FFDCA Permits Structure/Function Claims for Human and Animal Food

Premise:

Truthful and non-misleading nutritional information on food labeling has long been a pillar of food law, and is a central theme for the creation of the Federal Food, Drug and Cosmetic Act(FDCA), supported by NLEA and DSHEA. Consumer access to useful nutrition information helps them stay abreast of scientific developments and allows them to understand the important role of proper nutrition in long term health. The ability to provide this information on labeling is critical to the practical application of the science. Labeling of products that deliver health-diet related benefits must have the freedom to educate consumers, as supported by the First Amendment to the Constitution. The courts have ruled that regulatory agencies have the responsibility to support (or allow) such information for the benefit of man and animal. Therefore, access to this information should not be hindered.

In this case, the discussion refers to Structure/Function claims on animal feed, including pet food. Structure/Function claims describe the physiological interaction between food and bodily systems. Structure/Function claims can describe that interaction, or how the bodily system is maintained or improved.

Basis:

The statutory basis for allowing structure/function claims to be made, without being deemed drug claims, is Section 201(g) of the FFDCA. Section 201(g)(1)(c) defines a drug as "articles (*other than food*) intended to affect the structure or function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C) (emphasis added). The parenthetical carve out indicates that under the FFDCA, foods may be positioned to affect the structure or any function of the body of man or other animals without being categorized as drugs. Under the statute, the scope of the carve out for food-based structure/function claims is limited only by the definition of food. Food is defined as "articles used for food or drink for man *or other animals* . . . and articles used for components of any such article." 21 U.S.C. § 321(f)(1)(emphasis added). The definition of food makes clear that the carve out applies to both human and animal foods.

Production Claims:

Since the FFDCA allows the use of structure/function claims for "food", it is clear that these claims are as applicable to animal feed as to human food. Historically, for instance, production claims have been regulated as drug claims; however, this action was based on the inclusion of active compounds, e.g. sub-therapeutic use of antibiotics. However, there are now numerous nutritional practices that provide "food" bases for such things as improving weight gain or milk production, or increasing lean body mass, which are appropriate structure/function claims.

First Amendment:

For many decades the courts were willing to accept FDA's view that a purported structure/function claim amounted to nothing more than "unlawful speech" in that such claims

were implicitly viewed as implied drug claims. Indeed, as recently as the rulemakings implemented the Nutrition Labeling and Education Act of 1990 (NLEA) by FDA, reflected in the 1993 final regulations, FDA steadfastly defended its view that certain purported health claims amounted to no more than unlawful drug claims, citing decades of court decisions that claims deemed false or misleading by FDA enjoyed no First Amendment protection, and truthful and non-misleading claims were not allowed because them were deemed to be drug claims. However, the fundamental shift made by the courts in recent years, influenced not only by Congressional enactment of the NLEA and DSHEA but also the notion that it is not government's role to protect consumers from truthful information, reinforces the need for CVM to also necessarily shift the way in which it views and regulates structure/function claims so that the agency treats structure/function claims similarly. This is particularly true for pet foods since they are often found in commerce in conjunction with human foods, and the consumer expects the same types of labeling and information to be available.

Support:

The claim must be truthful and not misleading. Information to support a claim would include competent and reliable scientific information of the kind that a knowledgeable scientist would need to make an informed decision concerning the intended use of the product. Such supporting information can be derived from by way of example but not limited to, literature, applicable studies, tests, analyses, research, or other evidence. The food for which the claim is made must be safe for its intended use.

Finally, a "common knowledge" perspective should be considered in evaluating whether a claim is properly supported. The pet owner understands a great deal about claims related to their health for certain food items, and is bombarded on a daily basis with more information. For example, veterinarians and physicians have prescribed "bland diets" for GI tract upset for decades, while certain fatty acids have been known to help skin health. There is great value in allowing companies to talk to their consumers using cues or information that are routinely provided to them by their veterinarian. In each of these cases, truthful and non-misleading statements about the benefits of certain nutrients should be allowed where the health benefit is rooted in sound science.

Items for Consideration in Development of Guidelines:

1. <u>Definitions:</u>

   A. Disease- damage to an organ, part, structure or system of the body such that it does not function properly; or a state of health leading to such dysfunctioning, except that diseases resulting from essential nutrient deficiencies are not included in this definition, by statute (21CFR 101.93(g)).

   B. Food- (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Because this definition is somewhat circular, the courts were prompted to construe the definition to also include articles consumed primarily for their nutritive value, taste or aroma. This broadened view of a "food" arose in court cases involving whether ingredients marketed for their

"drug-like" effects could be defended against FDA's challenge that products were drugs on the basis that the ingredients were derived from traditional foods (e.g. legumes).

C. Nutritive Value- that being provided by orally ingested substances that replace or provide the building blocks for, or the technical effects of, substances or components occurring in the body. This includes assisting in the efficient functioning of nutritional processes and of other metabolic processes necessary for the normal maintenance of life, e.g. plant sterol and stanol esters (65 FR 54686, 54388 (September 8, 2000). Additionally, a substance which as a component of food is of value for cellular functions such that it provides catalytic support for protective reactions (e.g., inhibiting harmful processes- 56 FR 60537, 60542 (November 27, 1991).

Further, nutritive value is not limited to those substances known to be essential nutrients such as vitamins and minerals, but may also include, for example, non-essential but beneficial amino acids, fatty acids, and microbial flora. The scientific community's understanding of nutritive value is expanding and CFSAN has recognized phytosterols as having nutritive value in human food with respect to their cholesterol lowering properties.

D. Nutrient- compound(s) in food which provide nutritive value.

2. <u>Structure/Function Claims May Be Described As Claims That:</u>

A. Describe the role of a nutrient intended to affect structure or function in animals. For example, "calcium builds strong bones" and "taurine for a healthy heart" and "iron for building red blood cells".

B. Characterize the mechanism by which a nutrient acts to maintain such structure or function. For example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," "antioxidants boost healthy immune system", "carbohydrate to supply energy",

C. Describe general well-being from consumption of a food. For example, "supports healthy function of vital organs", "helps animals live long, healthy lives", "promotes total body health" "low fat, high fiber to help maintain a healthy weight", "helps promote a healthy urinary tract."

D. Describe a benefit related to a nutrient deficiency disease (like niacin deficiency and pellagra, or selenium deficiency and white muscle disease)

E. Claims an effect on a condition associated with a natural state or process

Some natural states or processes such as growth, pregnancy and aging, are not themselves diseases. The conditions associated with these states or processes can vary from common, relatively mild conditions, for which medical attention is not required, to serious conditions that can cause significant or permanent harm if not treated effectively. Statements made in regard to transitory conditions that by their nature do not progress or become established disease states should not be excluded from the definition of allowable structure/function claims.

Examples of acceptable structure/function claims would be “controlled levels of calcium to allow healthy bone growth in puppies”; while “helps prevent hip dysplasia” would be a disease claim. Additionally, “Vitamin E to improve vitality and alertness in the aging animal” and "Vitamin E to help avoid mild memory loss associated with aging," would be an acceptable structure/function claims while "relieves senile dementias in older animals" would be considered a disease claim. Another acceptable example would be “carbohydrates to regulate a healthy glycemic response”, whereas “relieves diabetes mellitus” would be considered a disease claim.

F. Describe relief of common or occasional conditions

Claims associated with common, relatively mild conditions, such as “occasional stomach upset, muscle weakness or overweight”, for which medical attention is not required, would be structure /function claims.

For example, "contains bland ingredients to help avoid occasional stomach upset”, is a structure / function claim while “helps avoid vomiting associated with influenza” would be a drug claim. Other examples of structure / function claims include “Vitamin E and omega 3 fatty acids to relieve dry, itchy skin” and “supplemented with omega 3 fatty acid to help reduce occasional pain”. The formation of hairballs by cats is a common, normal physiological response to ingestion of indigestible material; therefore food formulated using common food ingredients to relieve that response should not be considered a drug. Similarly, body odors or fecal odors are common, normal physiological conditions that can be manipulated by changes in nutrition. Therefore, claims for the use of nutrients to reduce odor should not be considered disease claims.

G. Describe the effect of improving animal production through the use of food and not the use of drugs.

There are claims shared by products for food-producing and non-food producing animals that are known as “production/performance claims”. These claims have traditionally been regulated as drug claims based on the use of active compounds, e.g. sub-therapeutic antibiotics. However, these same production effects can be obtained through nutritional manipulation of food and are thus structure/function claims. There presently are nutritionally based claims, such as the life stage nutritional adequacy statements for pet food which are de facto structure/function claims since they claim benefits for growth, gestation/lactation, maintenance, or all life stages. These claims are found on labels for food producing animals and others as statements of intended use.

For example, the claims “maintains body condition during lactation” or “increases lean body mass” are structure/function claims when achieved by use of a food.

Examples for other animals include: Maintain body condition during lactation by nutritional manipulation, all species; increasing lean body mass; and nutritional enhancement of exercise performance in athletic animals.

3. Disease Claims

Claims that a food “prevents” “mitigates,” “diagnoses,” “cures,” or “treats” a disease.

For example, "provides iron to reduce symptoms of parasitosis”, or “carbohydrate to reduce effects of hepatic encephalopathy" would be disease claims. In contrast, the mere reference of a condition or state that could in some fashion be associated with a more serious disease-state should not be classified as a disease merely because a broad inference can be drawn to include it. Further, as in humans, nutrients can supplement traditional medicinal therapies to reduce the instance of disease in animals. For example, reducing the risk of the disease may be achieved by affecting the structure or function of the animal through nutritional manipulation; i.e., certain foods can mitigate or reduce kidney or heart disease simply by reducing or adding certain nutrients.

4. The Boundaries between Structure/Function Claims and Disease Claims:

A. What determines explicit or implied disease claims? Major consideration – the context of the statement, decided from information on the label, will determine if the statement is considered to be a disease claim. If context of claim is related to maintaining current healthy status of an animal such would be a structure/function claim.

Descriptors such as “restore,” “support,” “maintain,” “raise,” “lower,” “promote,” “regulate,” “boost”, “improve” or “stimulate” would generally be acceptable as structure/function claims, unless, in the context they are used, they imply an effect on disease. Examples of acceptable structure/function claims include:

- To help restore your dog’s shiny coat.
- Nutrients to support a healthy immune system.
- Natural source of glucosamine to help maintain joint health.
- Optimum nutrition to raise performance levels.
- Specially formulated to promote good digestion.
- Helps regulate normal body weight.
- Helps boost your cat’s appetite.
- Breath freshening ingredients to improve occasional bad breath.
- Stimulates lipolysis.

Further, the use of language such as “this food may be used as an adjunct to the treatment of kidney disease (or cognitive disorder)” or “Use in the presence of kidney disease (or skin disease)” should not be perceived as disease claims.

B. Does the food claim to have an effect on a disease or class of diseases?

The claim is a disease claim if it mentions a specific disease or class of diseases. For example, a claim that a product is "protective against the development of cancer" or "cures kidney disease” would be a disease claim.

However, since it is understood that nutrients or combinations of nutrients can reduce the risk of health-related conditions; labeling that explains the relationship between nutrients and disease risk should be acceptable. This information would assist pet owners in making informed choices for their pet’s diet. For example, “Diets rich in animal protein may reduce the risk of certain feline urinary tract diseases” or ”diets limited in calories may reduce the risk of diabetes mellitus” would be structure/function claims.

C. Does the food claim to have an effect on signs or symptoms of disease?

A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state. An example of an implied disease claim is "relief of bronchospasm (asthma)."

Other signs or symptoms are associated with a wide range of disease and non-disease states and do not necessarily imply an effect on a specific disease (e.g., occasional diarrhea, vomiting, itching, inflammation). For example, although "improves cognitive ability" might imply treatment of dementia and "relieves stress and frustration" might imply treatment of anxiety disorders, both of these signs also are characteristic of non-disease states. So, if there is no context linking them to a disease, they would be appropriate structure/function claims.

D. Product Names

Two principles form the basis for the distinction between product names that are structure/function claims and those that are disease claims.

To be a structure/function claim:

(1) the name should not contain the name, or a recognizable portion of the name, of a disease; and

(2) the name should not use terms such as "cure," "treat," “diagnose”, "mitigate” or "prevent,"

A name such as "KidneyCure" is a disease claim because it is an implied disease claim for kidney disease treatment. However, in some cases, whether a product name is a disease claim will depend on context. For example, "Sensitive Stomach” could be considered a structure/function claim if the context of the labeling indicated that the product was easy to digest and recommended for animals that have occasional trouble digesting food.