PET FOOD INSTITUTE
2025 M Street, NW, Suite 800
Washington, DC 20036

(202) 367-1120
FAX (202) 367-2120
www.petfoodinstitute.org

November 8, 2012

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

Re: Docket No. FDA–2012–D–0755 - Draft Compliance Policy Guide Sec. 690.150 on Labeling and Marketing of Nutritional Products Intended for Use To Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats

The Pet Food Institute (PFI) thanks the U.S. Food and Drug Administration for the opportunity to submit comments regarding the draft Compliance Policy Guide (CPG) Section 690.150 published on September 10, 2012. PFI represents the companies that make over 98% of U.S. cat and dog food. More than half of U.S. households own a dog or cat, and the U.S. pet food industry supports the health and wellbeing of 84 million pet cats and 74 million pet dogs in the United States. Most pet food products on the market are designed to fulfill the nutritional needs of cats or dogs (i.e., are "complete and balanced"). Complete and balanced pet food products are the culmination of decades of research in the area of canine and feline nutrition and are developed with healthy animals in mind.

The unfortunate reality is that some pets develop health issues over the course of their lives, some of which are chronic. Careful management of food and nutrient intake has offered a means to provide nutritional support for the companion animal population since the early days of development of therapeutic products in 1948. Therapeutic animal diets have provided nutritional support for untold numbers of pet dogs and cats, which in turn provide health benefits to their owners.

Therapeutic animal diets are designed to be fed at the direction of a veterinarian, and it is beneficial for the veterinarian to monitor the performance of a pet on a particular therapeutic diet. Some therapeutic pet foods may not be nutritionally complete and balanced by design and could cause nutritional deficiencies or imbalances if fed to a healthy pet for an extended time. Nevertheless, such diets are appropriate when fed to a pet experiencing a health issue for which a given product was designed.

We suggest a change in the title of the Compliance Policy Guide and language regarding products "intended to diagnose, cure, mitigate, treat or prevent disease". These five terms are used by the FDA in statutory language to define a drug. The types of products described in this draft compliance policy guide are not drugs. Instead they are foods intended to assist in the nutritional

management of pets with certain health conditions. For these reasons, PFI feels a more appropriate title and description of these types of products is: "Nutritional Products Intended for the Dietary Management of Dogs and Cats with Health Conditions."

PFI appreciates the consideration FDA has given to recognizing the benefits that therapeutic diets provide to cats and dogs in less than ideal health condition. The industry is confident that FDA will continue to exercise enforcement discretion with respect to these products, and that therefore therapeutic products will remain on the market as a viable option for veterinarians to prescribe for the dietary management of dogs and cats with specific health conditions. PFI and its member companies support FDA's intent to protect pets and their owners from products that make unwarranted and unsupported drug claims that could harm the pet or waste consumer money. However, therapeutic diets can play an important role in the dietary management of certain health conditions.

We respectfully believe that FDA underestimates the burden of annual reporting in regard to only five companies being affected by the draft CPG. It may be true that only five companies are selling products through veterinarians, but based upon the overall concern, the number of companies selling these products in pet stores or other retail environments is more numerous. PFI feels that FDA should include any company making a product labeled that it is designed to diagnose, cure, mitigate, treat, or prevent disease in dogs and cats in the burden estimate for this draft CPG.

The key purpose of therapeutic animal diets is and always has been nutritional support for dogs or cats with specific diseases or conditions where nutritional needs are compromised or altered due to the condition. They are intended for the dietary management of these diseases or conditions and may or may not be nutritionally complete and balanced, based upon the formulation. PFI requests that FDA clarify in the "Background" section that the CPG is intended to apply to therapeutic pet food products, regardless of whether they are nutritionally complete and balanced or designed for intermittent feeding.

The following comments relate to specific sections of the draft Compliance Policy Guide. Section headings from the draft CPG are in bold typeface followed by PFI's input.

Section "III. Discussion; A. Appropriate Use of Product"

PFI agrees with these statements. These products should only be available to the public through licensed veterinarians with whom the purchaser has a valid Veterinary-Client-Patient Relationship (VCPR) as defined by the American Veterinary Medical Association (AVMA)

Section "III. Discussion; B. Availability of Product Labeling to the General Public"

PFI encourages FDA to allow statements on a label or labeling regarding the dietary management of specific conditions or diseases in order to assist veterinarians in prescribing appropriate therapeutic animal diets.

Section "III. Discussion; C. Feed Ingredients"

PFI encourages FDA to explain that there are two methods by which GRAS can be achieved: through "self-determination" and through "notification."

We urge FDA to reference not just the 2012 AAFCO *Official Publication*, but future editions as well when considering regulatory actions against undefined feed ingredients. AAFCO publishes its *Official Publication* annually, and each new edition generally includes newly defined or redefined ingredients. Referencing the 2012 AAFCO *Official Publication* in perpetuity would cause FDA's regulatory actions to get out of synch with the latest regulatory standards for pet food ingredients. Additionally, Regulation PF5(4) in the current 2012 AAFCO *Official Publication* specifies that the common or usual name of the ingredients shall be used for any ingredient for which no name and definition has been established.

PFI also suggests that it would be helpful to industry and regulators to include a notation about approved color additives in this section, as those components are not covered in this draft Compliance Policy Guide.

Section "III. Discussion; D. Drug Listing and Manufacturer Registration"

PFI agrees that no drug registration or drug listing should be required.

Section "IV. Enforcement Policy; 1. The product is made available to the public only through licensed veterinarians or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian."

PFI agrees with this requirement. Internet retailers selling therapeutic pet food should have a licensed veterinarian on staff along with a requirement that the veterinarian of the pet owner is consulted by the internet retail veterinarian on staff to assure the right product is purchased.

Section "IV. Enforcement Policy; 2. The product is not marketed as an alternative to approved new animal drugs."

We understand that the FDA intends to prohibit marketing materials that promote a therapeutic pet food in place of or instead of an approved new animal drug. PFI believes this intent should not limit the availability of a nutritional product for conditions that are also treated via drugs. It is important to remember that the primary function of therapeutic animal diets is to support the animal's health by providing food with specific nutritional formulas working through the animal's nutritional pathways. Therefore, there is no conflict as the veterinarian can recommend a new animal drug and/or a therapeutic food in the medical and nutritional management of the patient.

Pet food manufacturers should be allowed to share with veterinary professionals all indications and contraindications that may exist. Such information may be critical to safe use, and therefore such communication should not be seen as "marketing" a product as an alternative to an approved new animal drug.

Section "IV. Enforcement Policy; 3. The manufacturer is registered under section 415 of the FD&C Act."

PFI suggests that it may be helpful to note that the manufacturer maintains active registration under section 415 of the FD&C Act as there is now a reregistration requirement every two years. FDA might also include the term "bioterrorism" when describing the Section 415 requirements, as this is a term that is often most recognized by companies.

Section "IV. Enforcement Policy; 4. The product's labeling complies with all food labeling requirements for such products (see 21 CFR Part 501)."

Title 21 CFR Part 501 only pertains to information provided on the product label. It does not address labeling in general. Therefore we would recommend that the statement should be modified to read "The product's label complies with all food labeling requirements for such products (see 21 CFR Part 501)."

Section "IV. Enforcement Policy; 5. The product does not include indications for a disease claim (e.g., obesity, renal failure) on the label."

Since therapeutic animal diets are only available to the public through licensed veterinarians or under the direction of a veterinarian, PFI feels that the label should be allowed to denote that a product is intended for the nutritional management of animals with a particular disease state, which is relevant to the appropriate use by a veterinarian. Additionally, PFI believes that referring to the disease state in the product name should be allowed to facilitate proper recommendation by veterinarians, and thus should be acceptable on the label for this purpose. Both of these practices have been common for therapeutic diets for some time and have been helpful to veterinarians. We understand that the FDA is concerned about protecting the consumer from the ability to self-diagnose, but the therapeutic products are intended to be sold under the control of the veterinarian and they, the veterinarian, need to easily see which product by name is appropriate for the pet. PFI also notes that there is confusion among the industry as to which terms are prohibited from use on a therapeutic pet food label.

It is important to consider, for the reasons listed above, (i.e. therapeutic products are recommended to pet owners by licensed veterinarians and are not available to the public at large) the label itself is not a tool to market or advertise to the public.

Since FDA has existing pre-market authorization procedures for several types of claims (e.g., hairball, urinary, plaque/tartar), PFI expects the agency would explicitly exclude these types of claims from this CPG requirement.

Lastly, PFI hopes the agency would not include products designed to promote maintenance of a healthy weight or weight loss (e.g., "weight management", "weight loss", "reduced calorie" and similarly marketed pet food products) in this guidance. Weight loss products can be a tool to enable pet owners to reduce the weight of a pet that has exceeded its ideal body condition, whether purchased at a pet owner's discretion or at the direction of a veterinarian. Weight management products have been sold at retail for many years and are not designed nor required to be sold by the direction of a veterinary recommendation. Furthermore the Association of American Feed Control Officials (AAFCO) has developed rules for claims and

descriptive terms such as “lite”, “reduced calorie”, “lean” and “low fat” that creates consistency in the marketplace. PFI believes that FDA does not intend to alter the legal status of these types of products, particularly products designed for weight loss, but the mention of “obesity” in the CPG may create confusion and uncertainty in the marketplace. It would be helpful to pet owners, veterinarians and pet food companies if FDA were to clarify that the CPG is not meant to, nor does it, alter the legal status of pet food products designed to promote healthy weight maintenance, weight loss, or that are marketed as “lite”, “reduced calorie”, “lean,” “low fat”, etc.

Section “IV. Enforcement Policy; 6. Distribution of labeling and promotional materials with any disease claims for the product is limited so that it is provided only to veterinary professionals.”

PFI expects that the term “distribution” includes both print and digital distribution of materials.

Patient information brochures created by pet food manufacturers to be distributed only to veterinary professionals should be excluded from this requirement.

Section “IV. Enforcement Policy; 7. Electronic resources for the dissemination of labeling information and promotional materials are secured so that they are available only to veterinary professionals.”

General product information should be available to the public, with more specific information obtainable through a secure site available only to veterinarians. If labeling includes no disease claims, then companies should be able to provide truthful information to consumers about therapeutic products that are available through veterinarians. Truthful information present on the label and that is in compliance with this CPG should be allowed to be communicated to consumers.

Section “IV. Enforcement Policy; 8. The product contains only ingredients that are GRAS ingredients, approved food additives, or feed ingredients defined in the 2012 Official Publication of the Association of American Feed Control Officials.”

As previously mentioned in this public comment under Section III. Discussion; C. Feed Ingredients, PFI encourages FDA to explain that there are two methods by which GRAS can be achieved: through “self-determination” and through “notification.”

We urge FDA to reference not just in the 2012 AAFCO *Official Publication*, but future editions as well when considering regulatory actions against undefined feed ingredients. AAFCO publishes its *Official Publication* annually, and each new edition generally includes newly defined or redefined ingredients. Referencing the 2012 AAFCO *Official Publication* in perpetuity would cause FDA’s regulatory actions to get out of synch with the latest regulatory standards for pet food ingredients.

Additionally, Regulation PF5(4) in the current 2012 AAFCO *Official Publication* specifies that the common or usual name of the ingredients shall be used for any ingredient for which no name and definition has been established.

PFI also suggests that it would be helpful to industry and regulators to include a notation about approved color additives in this section.

Section "IV. Enforcement Policy; 9.*The label and labeling of the product is not false and misleading in other respect.*

PFI agrees that the label and labeling should not be false and misleading.

Comments on "Priority for enforcement attention"

Considering that these are meant to be in priority order, PFI would suggest that higher priority be given for those products that are made directly available to the public circumventing the veterinarian (#4).

PFI again would like to thank the agency for the opportunity to submit public comment on this draft Compliance Policy Guide. We are encouraged by and support FDA's efforts to prevent consumer fraud and hope the same philosophy will be uniformly applied to other pet products, including dietary supplements.

We look forward to continuing to work with the FDA to develop any further needed language to deal with this important category of pet food. Please do not hesitate to contact PFI for any further assistance or for any needed discussion.

Sincerely,

Duane Ekedahl
President Pet Food Institute