

# **EXHIBIT J**

# Pet Food

The Food and Drug Administration (FDA) regulates that can of cat food, bag of dog food, or box of dog treats or snacks in your pantry. The FDA's regulation of pet food is similar to that for other animal foods. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. In addition, canned pet foods must be processed in conformance with the low acid canned food regulations to ensure the pet food is free of viable microorganisms, see Title 21 Code of Federal Regulations, Part 113 (21 CFR 113).

## FDA Regulation of Pet Food

There is no requirement that pet food products have pre-market approval by the FDA. However, FDA ensures that the ingredients used in pet food are safe and have an appropriate function in the pet food. Many ingredients such as meat, poultry and grains are considered safe and do not require pre-market approval. Other substances such as sources of minerals, vitamins or other nutrients, flavorings, preservatives, or processing aids may be generally recognized as safe (GRAS) for an intended use (21 CFR 582 and 584) or must have approval as food additives (21 CFR 570, 571 and 573). Colorings must have approvals for that use as specified in 21 CFR 70 and be listed in Parts 73, 74, or 81. For more information about pet foods and marketing a pet food, see FDA's Regulation of Pet Food (</animal-veterinary/animal-health-literacy/fdas-regulation-pet-food>) and Information on Marketing a Pet Food Product (</animal-veterinary/animal-health-literacy/information-marketing-pet-food-product>).

## Labeling

Pet food labeling is regulated at two levels. The current FDA regulations require proper identification of the product, net quantity statement, name and place of business of the manufacturer or distributor, and proper listing of all the ingredients in the product in order from most to least, based on weight. Some states also enforce their own labeling regulations. Many of these regulations are based on a model provided by the Association of American Feed Control Officials (AAFCO). For more information about AAFCO (<http://www.aaeco.org/>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), please visit its website. For more information about labeling requirements, see Pet Food Labels - General (</animal-veterinary/animal-health-literacy/pet-food-labels-general>).

FDA also reviews specific claims on pet food, such as "maintains urinary tract health," "low magnesium," and "hairball control." Guidance for collecting data to make a urinary tract health claim is available in Guideline 55 (</animal-veterinary/guidance-industry/cvm-gfi-55-supportive-data-cat-food-labels-bearing-reduces-urinary-ph-claims-protocol-development>) on the CVM portion of the FDA internet site.

CVM DOES NOT recommend one product over another or offer guidance on individual pet health issues that are normally provided by the pet's veterinarian. Questions regarding your pets' health and/or the specific use of any veterinary drug, pet food, or other product should always be referred to your veterinarian.

## Recalls & Reporting Problems

- [Recalls \(/recalls-withdrawals\)](/recalls-withdrawals)
- [How to Report a Pet Food Complaint \(/animal-veterinary/report-problem/how-report-pet-food-complaint\)](/animal-veterinary/report-problem/how-report-pet-food-complaint)
- [PETNet: An Information Exchange For Pet Food Related Incidents \(/animal-veterinary/pet-food/petnet-information-exchange-pet-food-related-incidents\)](/animal-veterinary/pet-food/petnet-information-exchange-pet-food-related-incidents)
- [Melamine Pet Food Recall of 2007 \(/animal-veterinary/recalls-withdrawals/melamine-pet-food-recall-2007\)](/animal-veterinary/recalls-withdrawals/melamine-pet-food-recall-2007)

## Guidance Documents

- [CVM GFI #55 Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH Claims: Protocol Development \(/animal-veterinary/guidance-industry/cvm-gfi-55-supportive-data-cat-food-labels-bearing-reduces-urinary-ph-claims-protocol-development\)](/animal-veterinary/guidance-industry/cvm-gfi-55-supportive-data-cat-food-labels-bearing-reduces-urinary-ph-claims-protocol-development)
- [CVM GFI #122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores \(/media/70183/download\)](/media/70183/download)
- [CPG Sec. 690.150 Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats \(/media/83998/download\)](/media/83998/download)

## Federal Register Notices

- [Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Irradiation \(http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001\\_register&docid=01-8719-filed.pdf\)](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-8719-filed.pdf) - Docket No. 99F-2799, CVM 2000108. Pages 18539-18540 [FR Doc. 01-088719] April 10, 2001.

## Additional Information

- [Pet Food and Treats in Your Home \(/animal-veterinary/animal-health-literacy/pet-food-and-treats-your-home\)](#)
- [Jerky Pet Treats \(/animal-veterinary/news-events/fda-investigates-animal-illnesses-linked-jerky-pet-treats\)](#)
- [FDA and Pet Food \(video\) \(/animal-veterinary/animal-health-literacy/fda-and-pet-food-video\)](#)
- [Food and Drug Administration/Center for Veterinary Medicine Report on the Risk from Pentobarbital in Dog Food \(/about-fda/cvm-foia-electronic-reading-room/food-and-drug-administrationcenter-veterinary-medicine-report-risk-pentobarbital-dog-food\)](#)
- [Target Animal Safety Review Memorandum: Trace Metal Analysis of Commercial Pet Food for Toxic Metals \(/media/81895/download\)](#)
- [Title 21, Code of Federal Regulations \(CFR\) \(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm\)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm)

# Information on Marketing a Pet Food Product

Labels  
Product Name and Intended Species  
Quantity Statement  
Guaranteed Analysis  
Ingredients  
Statement of Nutritional Adequacy  
Feeding Directions  
Name and Address of Manufacturer or Distributor  
Product and Manufacturer Registration and Licensing

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You have developed a dog food or treat and want to manufacture and market it. Are there rules or requirements you should know about?

Yes, you should be aware of Federal and State rules governing the manufacture and sale of pet food products. This information applies whether you want to produce pet treats, gravies or other pet food items, and the information applies whether you are manufacturing the products in your house or in a commercial operation. The information applies to all pet food products sold in the United States. Here's an overview of information available about the Federal and State rules.

The FDA's regulation of pet food is similar to that for other animal food. There is no requirement that pet food products have premarket approval by the FDA. However, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that pet foods, like human foods, be pure and wholesome, safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled.

The best source of information about State rules is the Association of American Feed Control Officials (AAFCO). To promote uniform labeling requirements across all States and territories of the United States, AAFCO has developed a set of "Model Regulations for Pet Food and Specialty Pet Food" that are contained in AAFCO's Official Publication. Since the AAFCO "Model Regulations" were developed consistent with Federal requirements, they are a useful resource for information on the regulation of pet food.

If you are considering starting a pet food, pet treat, or other animal food business, either in your house or in a commercial establishment, you should consider visiting the Pet Food page on CVM's Website and getting a copy of AAFCO's Official Publication. The AAFCO publication is available either through a local library or by purchasing a copy from the AAFCO. Information on how to order the Official Publication is available at [www.aaeco.org](http://www.aaeco.org) (<http://www.aaeco.org>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>). The Official Publication is updated and published annually.

Here is some of the information provided in the AAFCO publication that prospective pet food product manufacturers and sellers will want to know about.

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## Labels

As stated above, the requirements for labeling pet foods, treats and other pet food items are specified in a section of AAFCO's Official Publication, entitled "Model Regulations for Pet Food and Specialty Pet Food." There are 11 "Model Regulations." Some will apply to home-manufactured treats and foods. "Model Regulation PF2," "Label Format and Labeling," gives the general information that should appear on product labels and refers to some of the other "Model Regulations" for more in-depth specifics.

Under the "Model Regulations," pet food products are expected to contain

- An appropriate product name;
- The species of pet(s) for which the product is intended;
- A quantity statement for the amount of food in the package or container;
- A guaranteed analysis;
- A list of all ingredients in the product;
- A statement of nutritional adequacy, if required;
- Feeding directions, if required; and,
- Name and address of the manufacturer or distributor

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## Product Name and Intended Species

According to the AAFCO publication, the name of the product should fairly represent what the product is. An example of a name that unfairly represents a product to be something other than what it is would be “Beef Juice Gravy for Dogs,” when the product was composed of water and corn starch. Often the species for which the product is intended is incorporated into the product name, such as the words “for Dogs” in the above example. It is recommended that the name of each species for which the product is intended be presented on the label in words, because pictures or vignettes may be insufficient to clearly indicate the species of intended use.

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## Quantity Statement

The quantity statement, which is probably better known as the “net weight” or “net contents” statement must appear in the bottom third of the “principal display panel.” This panel is the part of the label most likely to be displayed when the product is offered for sale. The quantity statement should be separated from other statements around it. The amount of separation or space above and below the quantity statement must be at least the height of the lettering used in the quantity statement. So, if you use ¼ in. lettering in the quantity statement, you should have a ¼ in. of clear space above and below the quantity statement. You should also have a clear space before and after the quantity statement that is two times the width of the letter N used in the word “Net” in “Net Contents” or “Net Quantity.”

Net contents are generally expressed in terms of weight or count for dry products and fluid measures for liquids. Weight should be in terms of avoirdupois (pounds, ounces) units. Metric units of weight (kilograms [kg] grams [g]) may be voluntarily expressed in parentheses after the avoirdupois units. Units of liquid measure should be in terms of U.S. gallon, or quart, pint and fluid ounce and subdivisions thereof. Metric units of volume (liters [L] or milliliters [ml]) may be voluntarily expressed in parentheses after the U. S. liquid measure.

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## Guaranteed Analysis

According to the AAFCO model regulations, all pet food products should have a section of the label titled “Guaranteed Analysis.” For most products, guarantees should be given for the minimum percentage of crude protein, the minimum percentage of crude fat, the maximum percentage of crude fiber and the maximum percentage of moisture.

Guarantees for other nutrients may be needed if the product is promoted as containing significant amounts—or being a good source—of specific nutrients. Other nutrients may also be guaranteed voluntarily as specified in “Model Regulation PF4.”

The values for nutrient content are determined by specific gravimetric (weight) and chemical analyses on representative samples of the product. These analyses can be obtained from various sources. First, there are commercial food and feed analysis laboratories throughout the United States that will do the analysis for a fee. Second, many land grant universities, or their agricultural extension offices, have forage or feed testing laboratories that may be able to perform the analyses for a fee or as a service to residents of the State. Third, some State feed control offices have a feed analysis laboratory associated with the office that may perform the analyses on request. The Official Publication lists the contact information for the feed control offices in each State.

A specific number (e.g., 21%), not a range (e.g., 18-25%), and a statement as to whether that number is a minimum or a maximum, should be stated for each guarantee. Values for minimum content indicate the product contains at least the amount listed and will analyze as containing at least that amount of the nutrient within the allowed analytical variation listed for that nutrient in the Official Publication. Values for maximum content indicate the product contains no more than the amount listed and will analyze as containing no more than that amount of the nutrient, again within the allowed analytical variation.

The guaranteed values should be representative of the actual nutrient content of the product and cannot be simply picked or set artificially low in the case of minimums, or high in the case of maximums.

Because it is unlikely that the exact same value for each nutrient will be obtained when different batches of the same formulation (recipe) of the product are analyzed, it is helpful to know what the typical variation is for each of the guaranteed nutrients. You can determine the variation by analyzing at least three—and preferably more—batches of the product to determine the variability for each nutrient being guaranteed. The exact number of batches analyzed will be determined by the available resources, the time between batches and the variability observed for the nutrient. If variability is large, more batches are required to assess the extent of the variability and to set guaranteed values with respect to the allowed analytical variances in the Official Publication. This is somewhat of an iterative process. If you are unsure of what to set for a particular guarantee based on actual analytical results, you should consider consulting individuals experienced in interpreting analytical results and variability.

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## Ingredients

All pet food products must have a section of the label containing a list of the ingredients in the product. All ingredients should be listed by their common or usual name, and in descending order of predominance by their weight in the product. All ingredients should be listed in the same size letters or type. Thus, the ingredient weighing the most in the product is listed first, the ingredient weighing the second most is listed second, and so on, until all ingredients are listed.

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## **Statement of Nutritional Adequacy**

Products that are clearly identified as “treats,” “snacks” or “supplements” are not required to have a statement of nutritional adequacy on their label. But nothing prevents you from voluntarily placing a statement of nutritional adequacy on your label.

According to the Official Publication, products that may be interpreted by statements on their label to be the sole source of daily nutrients, other than water, required by the animal to which the product is fed should have a statement informing the purchaser how it was determined that the product meets the animal’s daily nutrient needs for its stage of life as specified in “Model Regulation PF7,” sections (a), (b), or (c) or that the product is intended for intermittent or supplemental feeding only.

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## **Feeding Directions**

Products with a statement of nutritional adequacy indicating that the product will meet the nutritional requirements for one or more stages of life of the animal to which the product is fed, including treats, snacks, and supplements that make a claim for nutritional adequacy, should have feeding directions that are consistent with meeting the animal’s daily nutrient requirements from the product, according to AAFCO. Feeding directions should be in common terms of product usage that are practical for the average user to measure.

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## **Name and Address of Manufacturer or Distributor**

The manufacturer (i.e., if you make the product and sell it) or distributor (i.e., if you have the product made for you and sell it) must list their name and address on the product label. The address must include the street address, city, State, and zip code. The street address may be omitted if your firm is listed in the current city directory or telephone directory for the city listed on the label.

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## **Product and Manufacturer Registration and Licensing**

Most States require that products distributed in that State be registered or licensed (the term differs between the States) with the State’s feed control office. The Official Publication lists the name and address for the feed control official and office in each of the 50 States. The Official Publication also contains a table of fees charged by each State for registering or licensing products and facilities. If you sell product in a State or ship it direct to individual purchasers in a State as a result of Internet or mail-order sales, then the product should be registered in that State. The facility where your product is produced may also need to be registered with the FDA.

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