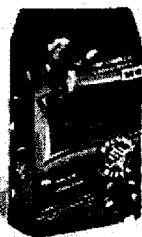




Try any one of our delicious canned or dry varieties for a taste your dog will love!

Kibbles 'n Bits dog food has the great taste dogs love and the 100% nutrition dogs need. Your dog will love every delicious bite of Kibbles 'n Bits dog food. And you'll love knowing he's getting complete and balanced nutrition!



BRUSHING BITES
Roasted Chicken & Vegetable Flavor



GOLDEN YEARS
Roasted Chicken & Vegetable Flavor



CANNED
Made with Real Meaty & Vegetables in a Rich Gravy



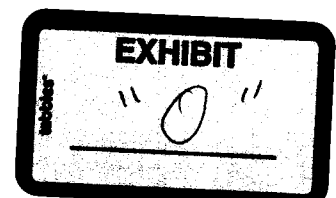
HOMESTYLE
Made with Real Meaty Pieces & Vegetables



ORIGINAL
Savory Chicken & Beef Flavor



MINI BITS
Specially Formulated for Puppies and Small Dogs





[KIBBLES 'N BITS® VARIETIES](#) | [FOR DOG LOVERS](#) | [DOG CARE CENTER](#)

[RETURN HOME](#)

[GIVE US YOUR FEEDBACK](#)

[Privacy Policy](#) | [Legal Statement](#) | [Visit Our Parent Company](#)
Copyright Del Monte Foods. All Rights Reserved.

]

EXHIBIT “P”

PURINA







Beneful
DOG FOOD

PRODUCTS DOG'S LIFE SHARE DOG STORIES PUPPY'S LIFE

ORIGINAL HEALTHY WEIGHT HEALTHY RADIANCE™ HEALTHY GROWTH HEALTHY HARVEST PREPARED MEALS™

Beneful® Original

A perfect balance of healthful ingredients, quality nutrition and superb taste for pure contentment for dogs

-  Moist, chewy chunks made with real beef are rich in quality protein to help build strong muscles.
-  Omega fatty acids, along with antioxidants like Vitamin E and selenium, help support a healthy immune system.
-  Enriched with calcium for healthy teeth and strong bones.
-  Crunchy corn packed with carbohydrates for energy and linoleic acid for a shiny coat.
-  Contains vegetables with Vitamin A and other quality vitamins, minerals, and nutrients.
-  Contains iron for healthy blood.



Guaranteed Analysis

Crude Protein (Min)	25.0%	Calcium (Ca) (Min)	1.1%
Crude Fat (Min)	10.0%	Iron (Fe) (Min)	200 mg/kg
Crude Fiber (Max)	4.0%	Selenium (Se) (Min)	0.2 mg/kg
Moisture (Max)	14.0%	Vitamin A (Min)	10,000 IU/kg
Linoleic Acid (Min)	1.5%	Vitamin E (Min)	100 IU/kg

CALORIE CONTENT

Metabolizable Energy (ME)
3689 kcal/kg
1674 kcal/lb
360 kcal/cup

Manufactured by: Nestlé Purina PetCare Company, St. Louis, MO 63164 USA

Animal feeding tests using Association of American Feed Control Officials (AAFCO) procedures substantiate that Beneful® dog food provides complete and balanced nutrition for all life stages.

Ingredients

Ground yellow corn, chicken by-product meal, corn gluten meal, whole wheat flour, beef tallow preserved with mixed-tocopherols (source of Vitamin E), rice flour, beef, soy flour, sugar, sorbitol, tricalcium phosphate, water, animal digest, salt, phosphoric acid, potassium chloride, dicalcium phosphate, sorbic acid (a preservative), L-Lysine monohydrochloride, dried peas, dried carrots, calcium carbonate, calcium propionate (a preservative), choline chloride, vitamin supplements (E, A, B-12, D-3), added color (Yellow 5, Red 40, Yellow 6, Blue 2), DL-Methionine, zinc sulfate, glyceryl monostearate, ferrous sulfate, niacin, manganese sulfate, calcium pantothenate, riboflavin supplement, biotin, thiamine mononitrate, garlic oil, copper sulfate, pyridoxine hydrochloride, folic acid, menadione sodium bisulfite complex (source of Vitamin K activity), calcium iodate, sodium selenite.
F-4090

SEARCH

[Terms and Conditions](#) [Privacy Policy](#) [Linking Policy](#) [Purina.com](#) [How Can We Help?](#)

All trademarks and other intellectual property on this site are owned by Société des Produits Nestlé S.A., Vevey, Switzerland

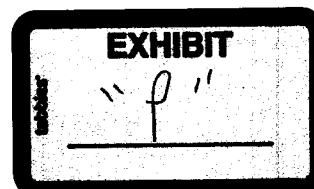


EXHIBIT “Q”



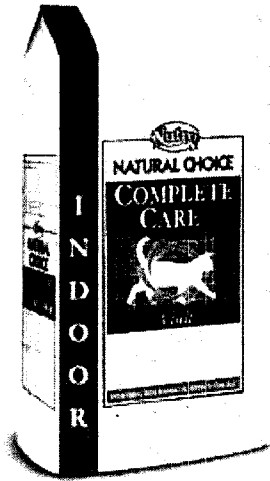
- NUTRO INFO
- PET CENTER
- DOG
- CAT
- PROGRAMS
- PROMOTIONS

HOME

WHERE TO BUY

PRODUCTS

HELP ME CHOOSE



Benefits of Natural Choice Complete Care Indoor Adult:

- For cats 1 to 6 years
- Scientifically formulated for the unique needs of indoor cats
- Guaranteed* to improve skin & coat for less shedding, fewer hairballs
- Advanced antioxidants for a healthy immune system
- Formulated to reduce litter box and in-home odor
- Natural ingredients with vitamins & minerals
- Recommended by veterinarians



Natural Choice Complete Care Product Center

Click on the links below to learn more about this product.

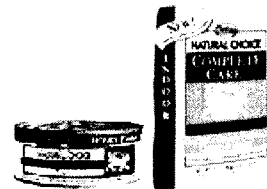
[Feeding Guide](#)

[Ingredients](#)

[Guaranteed Analysis](#)

[See the Food Image](#)

Try these other products!



Indoor Cats Have Special Nutritional Needs.

Indoor temperature, lighting and reduced opportunity for exercise can affect the health of your cat's skin and coat, muscle and bone condition and may cause weight gain. If your adult cat lives indoors most of the time, then feeding Natural Choice Complete Care Indoor Adult Formula can improve your cat's overall health and well-being.

Natural Choice Complete Care Indoor Adult is not just another cat food. Based on the latest scientific and nutritional research, our Indoor Adult formula is guaranteed to improve your indoor cat's skin and coat, reduce shedding, minimize hairballs, build strong muscles and bones and help limit excess weight gain*. It's formulated with unique ingredients like chicken meal, rice, sunflower oil, oat fiber and soy protein concentrate, which are especially important for indoor cats.

Healthy Growth for Indoor Cats

Guaranteed to Improve Skin & Coat*

A blend of nutrients, including high levels of linoleic acid, a healthy fatty acid proven essential for healthy skin and shiny coat, plus arachidonic acid (ARA), zinc and alpha-linolenic acid to help nourish the skin and make your kitten's coat shinier and more lustrous.

Less Shedding, Fewer Hairballs

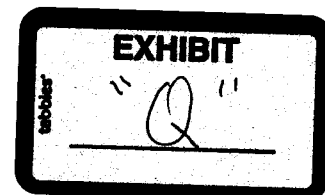
Healthy skin and coat helps minimize flaking and shedding which means there is less hair swallowed during self-grooming for reduced hairball formation. Plus, FiberClean, a special blend of rice and oat fiber, helps to pass any hair that is swallowed gently through the digestive system and into the litter box. With less swallowed hair irritating your cat's stomach, fewer hairballs are expelled.

Formulated to Reduce Litter Box Odor

Contains OdorCheck™ System, an innovative blend of ingredients that effectively reduce litter box odor for a fresh home environment. Helps make living with kittens more enjoyable.

Helps Cats Utilize Fat & Increases Energy

Our special WeightCare™ System with L-Carnitine helps indoor cats convert fat to energy and build lean muscle mass to offset your indoor cat's reduced activity and exercise levels. The result is increased energy and strong muscles for your indoor cat's overall health.



Nourishes Bones & Joints

Our exclusive BoneCare™ System helps develop strong bones and joints with calcium, phosphorus and manganese. Vitamin D enriched for better calcium absorption.

Natural Ingredients with Vitamins & Minerals

Made with an exclusive blend of the finest natural ingredients with vitamins and minerals, Natural Choice Complete Care provides optimal nutrition for your indoor cat. Fortified with iron to supply oxygen-rich red blood cells for stamina and energy and naturally preserved with Vitamin E to ensure freshness.

Advanced DentalCare™ System

Unique shape and texture helps scrub away plaque and tartar for healthy gums and teeth.

Easy To Digest for Sensitive Stomachs

Made with rice, the most digestible and gentle cereal grain—No ground corn. Made with high quality chicken protein for healthy digestion.

Advanced Antioxidants for a Healthy Immune System

A special blend of vitamins C, E, Beta-Carotene and Tocotrienols to help support the immune system for a long, healthy life. Antioxidants are known to help slow cellular damage from aging.

Nourishes Brain, Vision & Heart

Contains DHA and arachidonic acid (ARA) – nutrients essential for brain, vision and heart function to help keep cats alert. Taurine fortified for a healthy heart and good vision.

Great Taste Guaranteed*

With an ideally sized and shaped kibble for your kitten's mouth and added B vitamins for healthy appetite and metabolism, Natural Choice Complete Care Indoor Adult helps you make sure your kitten eats enough for proper nutrition and good health.

*or your money back

Feeding Guidelines

When you introduce Natural Choice Complete Care Indoor Adult Formula to your cat, it is always a good idea to mix it first with the old food for the first few days. Free choice feeding is recommended, and daily portions may vary according to your cat's age, weight and activity level. Place the total recommended amount in your cat's dish at the same time every day. This way your cat will nibble throughout the day, satisfying the natural instinct to eat smaller, more frequent meals. To realize all of the benefits that Natural Choice Complete Care Indoor has to offer, you should make it your cat's only source of nutrition. A supply of fresh drinking water should be provided at all times. See your veterinarian regularly.

Suggested Amounts To Feed Per Day (in cups)[†]

Weight of Cat (lbs.)	Amount to Feed
3 – 5	1/4– 3/8 cup
5 – 10	3/8 – 3/4 cup
10 – 15	3/4 – 1 1/4 cups
15 - 20	1 1/4 – 1 5/8 cups

[†]Use a standard 8 oz. measuring cup. A standard 8 oz. measuring cup holds 3.74 oz. of Natural Choice Complete Care Indoor Adult Formula.

Nutritional Adequacy Statement

Animal feeding tests using the AAFCO[‡] procedures substantiate that **Nutro Natural Choice Complete Care Indoor Adult Formula** provides complete and balanced nutrition for adult cat maintenance.

[‡]Association of American Feed Control Officials.

Ingredients

Chicken Meal, Ground Rice, Corn Gluten Meal, Rice Flour, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Sunflower Oil (preserved with mixed Tocopherols, a source of Vitamin E), Flaxseed, Tomato Pomace, Brewers Dried Yeast, Natural Flavors, Dried Plain Beet Pulp, Dried Vegetable Fiber (carrots, celery, beets, parsley, lettuce,

watercress and spinach), Potassium Chloride, Menhaden Fish Oil (preserved with mixed Tocopherols, a source of Vitamin E), Oat Fiber, Soy Protein Concentrate, Cranberry Powder, Choline Chloride, DL-Methionine, Taurine, Dried Egg Product, Zinc Sulfate, Ferrous Sulfate, Vitamin E Supplement, L-Carnitine, Inositol, Dried Bacillus Licheniformis Fermentation Extract, Dried Bacillus Subtilis Fermentation Extract, Dried Chicory Root, Yucca Schidigera Extract, Niacin, Copper Sulfate, Ascorbic Acid (source of Vitamin C), Manganous Oxide, Riboflavin Supplement (source of Vitamin B2), Beta-Carotene, Vitamin A Supplement, Calcium Iodate, Calcium Pantothenate, Vitamin B12 Supplement, Biotin, Pyridoxine Hydrochloride (source of Vitamin B6), Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Folic Acid, Sodium Selenite.

Nutro supports the safe, ethical and humane treatment of all animals.

Guaranteed Analysis

Crude Protein (minimum)	33.00%
Crude Fat (minimum)	14.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Ash (maximum)	7.25%
Linoleic Acid (minimum)	4.00%
Arachidonic Acid (ARA) (minimum)	0.05%
Calcium (minimum)	0.90%
Phosphorus (minimum)	0.80%
Magnesium (maximum)	0.085%
Iron (minimum)	200 mg/kg
Manganese (minimum)	35 mg/kg
Zinc (minimum)	250 mg/kg
Vitamin D (minimum)	1,200 IU/kg
Vitamin E (minimum)	250 IU/kg
Taurine (minimum)	0.20%
Alpha-Linolenic Acid (minimum)**	0.70%
Ascorbic Acid (minimum)**	50 mg/kg
Beta-Carotene (minimum)**	3.2 mg/kg
Docosahexaenoic Acid (DHA) (minimum)**	0.06%
L-Carnitine (minimum)**	150 mg/kg
Total Bacillus Species (minimum)** (Bacillus licheniformis, Bacillus subtilis)	565 million CFU ‡ /lb

**Not recognized as an essential nutrient by the AAFCO Cat Food Nutrient Profiles.
 ‡ Colony Forming Units

Package Sizes:

4 lb.	8 lb.	20 lb.
-------	-------	--------

Kibble



This is the approximate size and color of the kibble.

[Dogs](#) | [Cats](#) | [Where to Buy](#) | [Promotions](#) | [Press Releases](#) | [Information](#) | [Site Map](#) | [Contact Us](#)

Copyright ©2007 [Nutro Products, Inc.](#) All rights reserved. [Privacy policy.](#)

EXHIBIT “R”

MENU FOODS INCOME FUND



Home

Recall Information

Press Release

Cat Product Information

Dog Product Information

FAQ's for Consumers

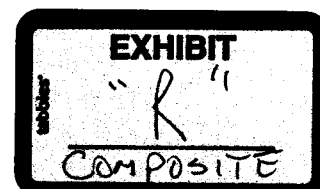
Recalled Dog Product Information Recall Information 1-866-895-2708

Variety or Multi-Packs:

If you are in possession of a variety or multi-pack, please be sure to check the individual can or pouch rather than relying solely on the date coding on the side of the carton.

Menu Foods Income Fund
8 Falconer Drive
Streetsville, ON
Canada L5N 1B1

1. [Americas Choice, Preferred Pets](#) Last Updated: May 2, 2007
2. [Authority](#) Last Updated: May 2, 2007
3. [Award](#) Last Updated: May 2, 2007
4. [Best Choice](#) Last Updated: May 2, 2007
5. [Big Bet](#) Last Updated: May 2, 2007
6. [Big Red](#) Last Updated: May 2, 2007
7. [Bloom](#) Last Updated: May 2, 2007
8. [Cadillac](#) Last Updated: May 2, 2007
9. [Companion](#) Last Updated: May 2, 2007
10. [Compliments](#) Last Updated: May 2, 2007
11. [Co-Op Gold](#) Last Updated: May 2, 2007
12. [Demoulas Market Basket](#) Last Updated: May 2, 2007
13. [Eukanuba](#) Last Updated: April 5, 2007
14. [Food Lion](#) Last Updated: May 2, 2007
15. [Giant Companion](#) Last Updated: May 2, 2007
16. [Grreat Choice](#) Last Updated: May 2, 2007
17. [Hannaford](#) Last Updated: May 2, 2007
18. [Health Diet Gourmet Cuisine](#) Last Updated: May 2, 2007
19. [Hill Country Fare](#) Last Updated: May 2, 2007
20. [Hy-Vee](#) Last Updated: May 2, 2007
21. [Iams](#) Last Updated: April 5, 2007
22. [La Griffre](#) Last Updated: May 2, 2007
23. [Laura Lynn](#) Last Updated: May 2, 2007
24. [Loving Meals](#) Last Updated: May 2, 2007
25. [Master Choice](#) Last Updated: May 2, 2007
26. [Meijers Main Choice](#) Last Updated: May 2, 2007
27. [Mighty Dog Pouch](#)
28. [Mixables](#) Last Updated: May 2, 2007
29. [Natural Life](#) Last Updated: May 3, 2007
30. [Nu Pet](#) Last Updated: May 2, 2007
31. [Nutriplan](#) Last Updated: May 2, 2007
32. [Nutro Max](#) Last Updated: May 2, 2007
33. [Nutro Natural Choice](#) Last Updated: May 2, 2007
34. [Nutro Ultra](#) Last Updated: May 2, 2007
35. [Nutro](#) Last Updated: May 2, 2007
36. [Ol'Roy Canada](#) Last Updated: May 2, 2007
37. [Ol'Roy US](#) Last Updated: May 2, 2007
38. [Paws](#) Last Updated: May 2, 2007
39. [Performatrin Ultra](#) Last Updated: May 3, 2007
40. [Pet Essentials](#) Last Updated: May 2, 2007



41. [Pet Pride - Good n Meaty](#) Last Updated: May 2, 2007
42. [Presidents Choice](#) Last Updated: May 2, 2007
43. [Price Chopper](#) Last Updated: May 2, 2007
44. [Priority Canada](#) Last Updated: May 2, 2007
45. [Priority US](#) Last Updated: May 2, 2007
46. [Publix](#) Last Updated: May 2, 2007
47. [Roche Brothers](#) Last Updated: May 2, 2007
48. [Save-A-Lot Choice Morsels](#) Last Updated: May 2, 2007
49. [Schnucks](#) Last Updated: May 2, 2007
50. [Shep Dog](#) Last Updated: May 2, 2007
51. [Springfield Prize](#) Last Updated: May 2, 2007
52. [Sprout](#) Last Updated: May 2, 2007
53. [Stater Brothers](#) Last Updated: May 2, 2007
54. [Stop & Shop Companion](#) Last Updated: May 2, 2007
55. [Tops Companion](#) Last Updated: May 2, 2007
56. [Triumph](#) Last Updated: May 2, 2007
57. [Truly](#) Last Updated: May 2, 2007
58. [Wegmans Bruiser](#) Last Updated: May 2, 2007
59. [Weis Total Pet](#) Last Updated: May 2, 2007
60. [Western Family Canada](#) Last Updated: May 2, 2007
61. [Western Family US](#) Last Updated: May 2, 2007
62. [White Rose](#) Last Updated: May 2, 2007
63. [Winn Dixie](#) Last Updated: May 2, 2007
64. [Your Pet](#) Last Updated: May 2, 2007

MENU FOODS INCOME FUND



[Home](#)

[Recall Information](#)

[Press Release](#)

[Cat Product Information](#)

[Dog Product Information](#)

[FAQ's for Consumers](#)

Recalled Cat Product Information Recall Information 1-866-895-2708

Variety or Multi-Packs:

If you are in possession of a variety or multi-pack, please be sure to check the individual can or pouch rather than relying solely on the date coding on the side of the carton.

Menu Foods Income Fund
8 Falconer Drive
Streetsville, ON
Canada L5N 1B1

1. [Americas Choice, Preferred Pets](#) Last Updated: May 2, 2007
2. [Authority](#) Last Updated: May 2, 2007
3. [Best Choice](#) Last Updated: May 2, 2007
4. [Cats Choice](#) Last Updated: May 3, 2007
5. [Companion](#) Last Updated: May 2, 2007
6. [Compliments](#) Last Updated: May 2, 2007
7. [Co-Op Gold](#) Last Updated: May 2, 2007
8. [Demoulas Market Basket](#) Last Updated: May 2, 2007
9. [Despar](#) Last Updated: May 2, 2007
10. [Drs Foster & Smith](#) Last Updated: May 3, 2007
11. [Eukanuba](#) Last Updated: April 5, 2007
12. [Fame](#) Last Updated: May 2, 2007
13. [Feline Classic](#) Last Updated: May 2, 2007
14. [Feline Cuisine](#) Last Updated: May 2, 2007
15. [Fine Feline Cat](#) Last Updated: May 2, 2007
16. [Food Lion](#) Last Updated: May 2, 2007
17. [Foodtown](#) Last Updated: May 2, 2007
18. [Giant Companion](#) Last Updated: May 2, 2007
19. [Giant Eagle](#) Last Updated: May 2, 2007
20. [Hannaford](#) Last Updated: May 2, 2007
21. [Hill Country Fare](#) Last Updated: May 2, 2007
22. [Hy-Vee](#) Last Updated: May 2, 2007
23. [Iams](#) Last Updated: April 5, 2007
24. [J.E. Mondou](#) Last Updated: May 2, 2007
25. [La Griffe](#) Last Updated: May 2, 2007
26. [Laura Lynn](#) Last Updated: May 2, 2007
27. [Li'l Red](#) Last Updated: May 2, 2007
28. [Loving Meals](#) Last Updated: May 2, 2007
29. [Master Choice](#) Last Updated: May 2, 2007
30. [Medi-Cal](#) Last Updated: May 2, 2007
31. [Meijer's Main Choice](#) Last Updated: May 2, 2007
32. [Natural Ultramix](#) Last Updated: May 2, 2007
33. [Nu Pet](#) Last Updated: May 2, 2007
34. [Nutriplan](#) Last Updated: May 2, 2007
35. [Nutro](#) Last Updated: May 2, 2007
36. [Nutro Max Gourmet Classics](#) Last Updated: May 2, 2007
37. [Nutro Natural Choice](#) Last Updated: May 2, 2007
38. [Nutro Products](#) Last Updated: May 2, 2007
39. [Paws](#) Last Updated: May 2, 2007
40. [Performatrin Ultra](#) Last Updated: May 3, 2007

41. [Pet Pride](#) Last Updated: May 2, 2007
42. [Presidents Choice](#) Last Updated: May 2, 2007
43. [Price Chopper](#) Last Updated: May 2, 2007
44. [Priority Canada](#) Last Updated: May 2, 2007
45. [Priority US](#) Last Updated: May 2, 2007
46. [Publix](#) Last Updated: May 2, 2007
47. [Roche Brothers](#) Last Updated: May 2, 2007
48. [Roundy's](#) Last Updated: May 2, 2007
49. [Save-A-Lot Special Blend](#) Last Updated: May 2, 2007
50. [Schnucks](#) Last Updated: May 2, 2007
51. [Science Diet Feline Savory Cuts Cans](#) Last Updated: April 12, 2007
52. [Sophistacat](#) Last Updated: May 2, 2007
53. [Special Kitty Canada](#) Last Updated: May 2, 2007
54. [Special Kitty US](#) Last Updated: May 2, 2007
55. [Springfield Prize](#) Last Updated: May 2, 2007
56. [Sprout](#) Last Updated: May 2, 2007
57. [Stop & Shop Companion](#) Last Updated: May 2, 2007
58. [Stuzzy Gold](#) Last Updated: May 2, 2007
59. [Tops Companion](#) Last Updated: May 2, 2007
60. [Triumph](#) Last Updated: May 2, 2007
61. [Wegmans](#) Last Updated: May 2, 2007
62. [Weis Total Pet](#) Last Updated: May 2, 2007
63. [Western Family Canada](#) Last Updated: May 2, 2007
64. [Western Family US](#) Last Updated: May 2, 2007
65. [White Rose](#) Last Updated: May 2, 2007
66. [Winn Dixie](#) Last Updated: May 3, 2007
67. [Your Pet](#) Last Updated: May 2, 2007

EXHIBIT “S”



U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#) | [FDA Centennial](#)

INFORMATION FOR CONSUMERS

FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

FDA's REGULATION OF PET FOOD

*The following consumer information is provided by Sharon Benz, Ph.D., P.A.S.,
Division of Animal Feeds, Center for Veterinary Medicine*

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act, a part of FDA's responsibility is to ensure that human and animal foods are safe and properly labeled. Within FDA, the Center for Veterinary Medicine is responsible for the regulation of animal drugs, medicated feeds, food additives and feed ingredients, including pet foods. The regulations based, in part, on this law are found in the *Code of Federal Regulations*, Title 21, Food and Drugs, Part 500.

The Act is this country's basic food and drug law. It defines food as "articles used for food or drink for man or other animals...and articles used for components of any such article." There is no requirement that pet foods have pre-market approval by FDA. The Act does require that pet foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled. Additionally, canned pet foods must be processed in conformance with low acid canned food regulations (Title 21, *Code of Federal Regulations*, Part 113, abbreviated as 21 CFR 113).

In the Act a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article intended to affect the structure or function of the body other than food (Sec. 201 (g)(1)). In the drug definition, the courts have interpreted "food" as something that provides nutrition, taste, or aroma. If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure or taurine for healthy heart function in cats). However, if a substance affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug. Structure/function effects extending beyond the "food" umbrella also include claims for improved or increased production and performance, or alteration or improvement in function.

When a substance, including one considered food, is intended to be used for the treatment or prevention of disease or "non-food" structure/function effect, FDA considers it a drug. Under the law, a new animal drug must be shown to be safe and effective for its intended use by adequate data from controlled scientific studies as part of a New Animal Drug Application (21 CFR, Part 514). If a product on the market is not approved, it may be deemed an adulterated drug and subject to regulatory action.

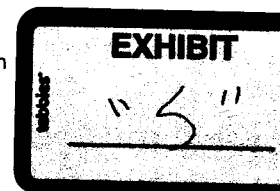
In 1958, in response to public concern about the increased use of chemicals in foods and food processing, Congress amended the Act to require the pre-marketing clearance of additives whose safety was not generally recognized. The Act was also amended to deem food unsafe and adulterated if it contains an unapproved food additive. Under the definition for food additive in Sec. 201 (s) of the Act, it provides that substances added to food that qualified scientists generally recognize as safe (GRAS) under the conditions of the intended use are not "food additives" and as such are exempt from pre-clearance approval.

A food additive petition is the pre-clearance mechanism developed by the FDA for demonstrating that a food additive is safe for its intended use and has utility. If the FDA agrees with the petition, a regulation is published in the *Federal Register* and 21 CFR, Part 573, Food Additives Permitted in the Feed and Drinking Water of Animals, is amended. The information needed in a food additive petition is described in Part 571 of Title 21. Briefly, a petition contains a description of the chemical identity, manufacturing process and controls, analytical methods, utility data, human food safety data, target animal safety data, product labeling, and in some cases an environmental assessment.

CVM has used regulatory discretion and not required food additive petitions for substances that do not raise any safety concerns. In this case, we ask the company to submit the information needed to list the ingredient in the *Official Publication of the Association of American Feed Control Officials (AAFCO)*. This ingredient definition process is done to conserve agency resources, as food additive approval is time-consuming. CVM reviews the data to ensure the ingredient has utility and can be manufactured consistently to meet product specifications. Although ingredients used under regulatory discretion are still unapproved food additives, we agree we will not take regulatory action as long as the labeling is consistent with the accepted intended use, the labeling or advertising does not make drug claims, and new data are not received that raise questions concerning safety or suitability.

A GRAS substance is GRAS only for an intended purpose. For example, sodium aluminosilicate is GRAS as an anticaking agent. It has been purported to bind mycotoxins and prevent absorption from the intestinal tract but would not be GRAS for this use. A food substance also cannot be GRAS for the prevention, treatment, or mitigation of a disease. So, chondroitin sulfates cannot be GRAS to prevent or treat arthritis. For this use it would be a drug.

It is very important to recognize that general recognition of safety of a substance for an intended use may only be based on



the views of experts qualified by scientific training and experience to evaluate the safety of the substance. As interpreted by FDA and the courts, there are two requirements that must be satisfied before a substance can be GRAS – general recognition and safety:

1. For general recognition, there must be an expert consensus that the substance is safe for use as a component of food, and;
2. This expert consensus of safety must be based on either (a) generally available data and information to show common use of the substance in animal feed prior to 1958 or (b) scientific procedures, which require the same quantity and quality of scientific data needed for FDA approval of the substance as a food additive. In addition, this information must be published in the scientific literature.

Both of these requirements, general recognition and safety, must be met for a substance to be considered as GRAS. The GRAS standard is actually more stringent than that required for a food additive approval because for a substance to be GRAS there must exist the same quality and quantity of information needed for a food additive approval. In addition, the data must be published and there must be a consensus among qualified experts, based on the data, that the substance is safe for that use. Publication of data in a company's annual report does not meet the publication standard. For general recognition of safety to exist, the data must be available to the experts by publication in the scientific literature. The Act permits companies to make their own GRAS determination, and many times GRAS Panels will be assembled that are comprised of scientific experts in a particular field to evaluate the safety of a substance for an intended use. However, regardless of who makes the determination, the FDA or the company, the standard for GRAS is the same.

On April 17, 1997, the Center for Food Safety and Applied Nutrition (CFSAN) and CVM published a proposed rule in the *Federal Register* (62 FR 18938) to amend the regulations to replace the current GRAS affirmation process with a notification procedure. Under the notification procedure, any person could notify the agency of a determination that a particular use of a substance is GRAS. The notification would include a description of the substance, the conditions of use, and the basis of the GRAS determination. The FDA would not conduct its own detailed evaluation of the data, as was done previously for GRAS affirmation petitions. Rather, FDA would evaluate whether the notice provides sufficient basis for a GRAS determination and whether the information in the notification or otherwise available to FDA raises issues on whether the use of the substance is GRAS. In the proposal FDA would have 90 days to respond to the notifier. The summary of the GRAS notifications would be available on the FDA Home Page, as would the FDA's responses to the person submitting the notification. CVM is not currently accepting GRAS notifications under the proposed rule; however, CFSAN is. A listing of the notifications that have been submitted can be found on <http://www.cfsan.fda.gov/~dms/>.

Once the final rule is published, CVM will accept GRAS notifications. It is anticipated that GRAS notifications submitted for use of substances in animal feed will be posted on the [CVM Home Page](#). When a GRAS notification raises no issue of concern to CVM, the AAFCO Feed Ingredient Chair will be notified so that the substance and its use can be listed in the AAFCO publication.

The Dietary Supplement and Health Education Act

When Congress enacted the Dietary Supplement and Health Education Act (DSHEA) on October 25, 1994, it created a new category of substances and new regulatory scheme. The Act was amended to define a dietary supplement as a product intended to supplement the diet and that contains at least one or more of the following ingredients: a vitamin; a mineral; a herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of the previously mentioned ingredients (Sec. 201 (ff) of the Act). The main effect of DSHEA was to remove certain dietary ingredients from regulation as food additives, which requires pre-market approval. On April 22, 1996, CVM published a notice in the *Federal Register* outlining the reasons why FDA believes that Congress did not intend DSHEA to apply to substances for use in animals. This has been upheld in at least one court case. Thus, substances marketed as dietary supplements for humans still fall under the pre-DSHEA regulatory scheme when marketed for animals; that is, they are considered food, food additives, new animal drugs, or GRAS depending on the intended use. Most of these types of products on the market would be considered unapproved and unsafe food additives or new animal drugs based on current intended uses.

It is important to note that DSHEA defines the term "dietary supplement" to exclude products intended for use as conventional foods. For example, St. John's Wort would not be considered a dietary supplement if it were added to soup. Soup is a conventional food and any ingredient added to conventional foods must be used in accordance with the food additive regulation or be GRAS.

Health Claims

Congress also amended the Act when it enacted the Nutrition Labeling and Education Act in 1990. This law required FDA to write regulations to permit health claims on human food. A number of these claims have been approved for various foods. These can be found on the CFSAN web page.

CVM has incorporated the philosophy of NLEA in its policies in order to permit meaningful health information on pet foods. Examples are the use of urinary tract health claim on cat food diets, and development of AAFCO regulations for light, lean, less or reduced calories, lean, and less or reduced fat. Recently, CVM has been asked about complete cat foods for the control of hairballs. We would likely not take regulatory action provided the effect is achieved by ingredients already permitted for use in cat food, such as fiber sources. In this case, we ask that the firm submit information for review on the quantitative diet formulation, nutrient analysis, and labeling, and discussion on the basis for the claim, i.e., scientific studies or common knowledge of ingredients biological properties. If novel ingredients are used to achieve the effect, then we believe data demonstrating ingredient safety should be obtained prior to marketing.

Interaction with AAFCO

FDA also plays an active role in pet food regulation in partnership with AAFCO. An FDA representative serves on the

AAFCO Board of Directors. FDA has served on the Pet Food Committee. CVM staff also serves on other standing AAFCO committees and as investigators. We believe that continued partnership with AAFCO is vital to the effective regulation of pet food products because FDA has limited enforcement resources that are focused on human food safety issues. For this reason, an important role of CVM staff is to serve as scientific resources for State regulatory officials.

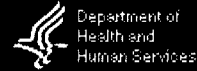
Summary

In summary, within the FDA, CVM has primary responsibility for enforcing the Act to ensure that animal foods, including pet foods, are safe and labeled appropriately and animal drugs are safe and effective. While FDA has tried to incorporate some of the philosophy of NLEA to permit health claims for pet foods, we believe that DSHEA was not intended by Congress to apply to animal foods. Thus, substances sold as dietary supplements for humans may not be legally distributed for use in animals unless the substances are food, approved animal food additives, GRAS, or approved new animal drugs.

EXHIBIT “T”



U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#) | [FDA Centennial](#)

[MUMS](#) | [Antimicrobial Resistance](#) | [Biotechnology](#) | [Aquaculture](#) | [Food Safety](#) | [BSE](#) | [Guidance Documents](#) | [Green Book](#) | [Freedom of Information](#)

Search



Powered by Google

CVM and Animal Food, Feed Ingredients, and Additives

Biotechnology Products

Biotechnology products are a growing proportion of the feed components regulated by the Center for Veterinary Medicine. We anticipate that "new" biotechnology will become an even greater source of products in the future. The spectrum of products being presented to CVM for regulation includes biotechnology products from plants, microbes and animals. For more information about the uses of products produced using this technology, see the [CVM Biotechnology in Animals and Animal Feeds](#) page.

Table of Contents

- [Animal Feed](#) ●
- [Product Regulation](#) ●
- [Biotechnology Products](#) ●
- [Feed Contaminants](#) ●
- [Survey Assignments](#) ●
- [Feed Ingredients](#) ●
- [Food Additives](#) ●
- [Feed Mill Licensing](#) ●
- [Import and Export](#) ●
- [Pet Foods](#) ●
- [Veterinary Feed Directive](#) ●
- [Prior Notice](#) ●
- [Food Facility Registration](#) ●
- [Animal Feed Safety Sys](#) ●
- [More Information](#) ●

Feed Contaminants

There are two classes of feed contaminants. The first is a toxic or deleterious substance that is an inherent, naturally occurring constituent of an animal food and is not the result of environmental, agricultural, industrial or other contaminations. Examples of this class include some of the mycotoxins, such as aflatoxin and fumonisin, the glucosinolates, and the heavy metals, like lead and cadmium. The second class is made up of industrial toxic or deleterious substances, which are not naturally occurring and are increased to abnormal levels in the animal food through mishandling or other intervening acts. Examples of this class are the polychlorinated biphenyls (PCBs) and certain pesticides, like DDT (1,1'-(2,2,2-Trichloroethylidene)bis[4-chlorobenzene]). CVM may prohibit any detectable amount of a contaminant or establish a regulatory limit for the contaminant, taking into account the protection of the public health, the extent to which the presence of the contaminant cannot be avoided, and other ways in which the consumer may be affected by the presence of the contaminant.

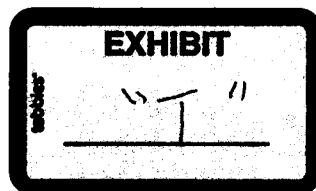
- [CVM Compliance Program Guidance Manual 7371.003 Feed Contaminants Program](#)

CVM Feed Sampling Survey Assignments

- [Nationwide Survey of Distillers Grains for Aflatoxins, November 21, 2006](#)
- [Nationwide Assignment to Collect Samples of Direct-Human-Contact Feeds and Analyze Them for Salmonella and E. coli O157:H7, October, 17, 2006](#)

Additional Information

- [Mycotoxins in Feeds: CVM's Perspective Presentation by Michael H. Henry, Ph.D. to the Risk Management Agency, August 23, 2006](#)
- [CVM Update - Animal Feed Safety System Website Posted, March 29, 2006](#)
- [Animal Feed Safety System 2005 Public Meeting, April 5 – 6, 2005 Crowne Plaza Hotel, Omaha, NE](#)
- [FDA Animal Feed Safety System \(AFSS\) Public Meeting, September 23-24, 2003 Hyatt Dulles International Airport, Herndon, VA](#)
- [Docket No. 94D-0147, CVM 200035. Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds; Availability. Pages 70752-70753 \[FR Doc. 02-29925\] November 26, 2002 | \[htm\]\(#\) | | \[pdf\]\(#\) |](#)



- [Guidance for Industry #80: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds, November 21, 2002 | pdf | doc |](#)

Feed Ingredients

A feed ingredient is a component part or constituent or any combination/mixture added to and comprising the feed. Feed ingredients might include grains, milling byproducts, added vitamins, minerals, fats/oils, and other nutritional and energy sources. Animal feeds provide a practical outlet for plant and animal byproducts not suitable for human consumption. The Official Publication of the Association of American Feed Control Officials (AAFCO) contains a list of feed ingredients with their definitions. Many of these ingredients are not approved food additives and may not meet the criteria needed to be recognized as GRAS (21 CFR 570.30). Nevertheless, FDA has not objected to the listing of certain ingredients (e.g., those used as sources of nutrients, aroma, or taste) in the AAFCO Official Publication or their marketing in interstate commerce, provided there were no apparent safety concerns about the use or composition of the ingredient.

Federal regulations require ingredients be listed on the product label by their common or usual name in descending order of predominance according to weight (21 CFR 501.4). A common or usual name is one that accurately identifies or describes the basic nature of the ingredient (21 CFR 502.5). FDA has recognized the definitions as they appear in the Official Publication of AAFCO as the common or usual name for animal feed ingredients including pet food ([Compliance Policy Guide 7126.08](#)). There is only one exception to the requirement to list the common or usual name on the label—when the ingredient is part of a collective name. Regulation 21 CFR 501.110 describes the use of collective names. The following are acceptable collective names: animal protein products, forage products, grain products, plant protein products, processed grain byproducts and roughage products. These collective names may be used in the ingredient list for livestock and poultry feeds, but not pet foods.

Association of American Feed Control Officials (AAFCO)

AAFCO is composed of state, federal, and international regulatory officials who are responsible for the enforcement of state laws regulating the safe production and labeling of animal feed, including pet food. FDA and AAFCO work together in the area of feed regulation, particularly in the establishment of definitions to describe new feed ingredients. Each year AAFCO publishes its Official Publication which includes a model feed bill for states to adopt in regulating feed products and a list of accepted feed ingredients. Most states have adopted all or part of the model feed bill and allow feed ingredients listed in the publication to be used in their respective territories. For more information about AAFCO, please see its internet site

Food Additives (Food Additive Petitions)

Any substance intentionally added to an animal feed, including pet food, must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use. The basis of a food additive regulation is an approved food additive petition. The food additive petition should include an adequate factual basis to establish that the food additive is safe for its intended use, under the conditions of use specified in the petition. If the petitioner meets this burden of proof, the food additive can be approved for use in animal feed.

There are several types of food additives based on its composition and intended use. A food additive generally provides one or more of the following, i.e., nutrient, aroma/ flavor, taste, soluble or insoluble fiber, stabilizer, emulsifier, sequestrant, chemical preservative, anti-oxidant, anti-caking agent, etc.

Section 571 of Part 21 of the Code of Federal Regulations (CFR) prescribes the kinds of data that must be submitted by the petitioner and the format which the food additive petition must follow when sent to FDA. While the actual content may vary from petition to petition, depending primarily on the food additive's composition and intended use, each of the following subject areas must be addressed: human food safety, target animal safety, environmental impact, utility, labeling, proposed regulation, assay methodology, and manufacturing process and controls. Subsequently, when the FDA concludes that the available data for a food additive are sufficient to meet current criteria, the FDA issues a regulation permitting the petitioned use of the additive.

- [CVM Update - FDA Permits the Use of Selenium Yeast in Horse Feed, October 14, 2004](#)

EXHIBIT “U”



U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#)INFORMATION FOR CONSUMERS
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

INTERPRETING PET FOOD LABELS

The following consumer information is provided by David A. Dzanis, DVM, Ph.D., DACVN.

Pet food labeling is regulated at two levels. The Federal regulations, enforced by the FDA's Center for Veterinary Medicine (CVM), establish standards applicable for all animal feeds: proper identification of product, net quantity statement, manufacturer's address, and proper listing of ingredients. Some States also enforce their own labeling regulations. Many of these have adopted the model pet food regulations established by the Association of American Feed Control Officials (AAFCO). These regulations are more specific in nature, covering aspects of labeling such as the product name, the guaranteed analysis, the nutritional adequacy statement, feeding directions, and calorie statements.

Product Name

The product name is the first part of the label noticed by the consumer, and can be a key factor in the consumer's decision to buy the product. For that reason, manufacturers often use fanciful names or other techniques to emphasize a particular aspect. Since many consumers purchase a product based on the presence of a specific ingredient, many product names incorporate the name of an ingredient to highlight its inclusion in the product. The percentages of named ingredients in the total product are dictated by four AAFCO rules.

The "95%" rule applies to products consisting primarily of meat, poultry or fish, such as some of the canned products. They have simple names, such as "Beef for Dogs" or "Tuna Cat Food." In these examples, at least 95% of the product must be the named ingredient (beef or tuna, respectively), not counting the water added for processing and "condiments." Counting the added water, the named ingredient still must comprise 70% of the product. Since ingredient lists must be declared in the proper order of predominance by weight, "beef" or "tuna" should be the first ingredient listed, followed often by water, and then other components such as vitamins and minerals. If the name includes a combination of ingredients, such as "Chicken 'n Liver Dog Food," the two together must comprise 95% of the total weight. The first ingredient named in the product name must be the one of higher predominance in the product. For example, the product could not be named "Lobster and Salmon for Cats" if there is more salmon than lobster in the product. Because this rule only applies to ingredients of animal origin, ingredients that are not from a meat, poultry or fish source, such as grains and vegetables, cannot be used as a component of the 95% total. For example, a "Lamb and Rice Dog Food" would be misnamed unless the product was comprised of at least 95% lamb.

The "25%" or "dinner" rule applies to many canned and dry products. If the named ingredients comprise at least 25% of the product (not counting the water for processing), but less than 95%, the name must include a qualifying descriptive term, such as "Beef Dinner for Dogs." Many descriptors other than "dinner" are used, however. "Platter," "entree," "nuggets" and "formula" are just a few examples. Because, in this example, only one-quarter of the product must be beef, it would most likely be found third or fourth on the ingredient list. Since the primary ingredient is not always the named ingredient, and may in fact be an ingredient that is not desired, the ingredient list should always be checked before purchase. For example, a cat owner may have learned from his or her finicky feline to avoid buying products with fish in it, since the cat doesn't like fish. However, a "Chicken Formula Cat Food" may not always be the best choice, since some "chicken formulas" may indeed contain fish, and sometimes may contain even more fish than chicken. A quick check of the ingredient list would avert this mistake.

If more than one ingredient is included in a "dinner" name, they must total 25% and be listed in the same order as found on the ingredient list. Each named ingredient must be at least 3% of the total, too. Therefore, "Chicken n' Fish Dinner Cat Food" must have 25% chicken and fish combined, and at least 3% fish. Also, unlike the "95%" rule, this rule applies to all ingredients, whether of animal origin or not. For example, a "Lamb and Rice Formula for Cats" would be an acceptable name as long as the amounts of lamb and rice combined totaled 25%.

The "3%" or "with" rule was originally intended to apply only to ingredients highlighted on the principal display panel, but outside the product name, in order to allow manufacturers to point out the presence of minor ingredients that were not added in sufficient quantity to merit a "dinner" claim. For example, a "Cheese Dinner," with 25% cheese, would not be feasible or economical to produce, but either a "Beef Dinner for Dogs" or "Chicken Formula Cat Food" could include a side burst "with cheese" if at least 3% cheese is added. Recent amendments to the AAFCO model regulations now allow use of the term "with" as part of the product name, too, such as "Dog Food With Beef" or "Cat Food With Chicken." Now, even a minor change in the wording of the name has a dramatic impact on the minimum amount of the named ingredient required, e.g., a can of "Cat Food With Tuna" could be confused with a can of "Tuna Cat Food," but, whereas the latter example must contain at least 95% tuna, the first needs only 3%. Therefore, the consumer must read labels carefully before purchase to ensure that the desired product is obtained.

Under the "flavor" rule, a specific percentage is not required, but a product must contain an amount sufficient to be able to be detected. There are specific test methods, using animals trained to prefer specific flavors, that can be used to confirm this claim. In the example of "Beef Flavor Dog Food," the word "flavor" must appear on the label in the same size, style and

EXHIBIT

"U"

color as the word "beef." The corresponding ingredient may be beef, but more often it is another substance that will give the characterizing flavor, such as beef meal or beef by-products.

With respect to flavors, pet foods often contain "digests," which are materials treated with heat, enzymes and/or acids to form concentrated natural flavors. Only a small amount of a "chicken digest" is needed to produce a "Chicken Flavored Cat Food," even though no actual chicken is added to the food. Stocks or broths are also occasionally added. Whey is often used to add a milk flavor. Often labels will bear a claim of "no artificial flavors." Actually, artificial flavors are rarely used in pet foods. The major exception to that would be artificial smoke or bacon flavors, which are added to some treats.

Net Quantity Statement

The net quantity statement tells you how much product is in the container. There are many FDA regulations dictating the format, size and placement of the net quantity statement. None of these do any good if the consumer does not check the quantity statements, especially when comparing the cost of products. For example, a 14-ounce can of food may look identical to the one-pound can of food right next to it. Also, dry products may differ greatly in density, especially some of the "lite" products. Thus, a bag that may typically hold 40 pounds of food may only hold 35 pounds of a food that is "puffed up." A cost-per-ounce or per-pound comparison between products is always prudent. **Manufacturer's Name and Address** The "manufactured by..." statement identifies the party responsible for the quality and safety of the product and its location. If the label says "manufactured for..." or "distributed by..." the food was manufactured by an outside manufacturer, but the name on the label still designates the responsible party. Not all labels include a street address along with the city, State, and zip code, but by law, it should be listed in either a city directory or a telephone directory. Many manufacturers also include a toll-free number on the label for consumer inquiries. If a consumer has a question or complaint about the product, he or she should not hesitate to use this information to contact the responsible party. **Ingredient List** All ingredients are required to be listed in order of predominance by weight. The weights of ingredients are determined as they are added in the formulation, including their inherent water content. This latter fact is important when evaluating relative quantity claims, especially when ingredients of different moisture contents are compared.

For example, one pet food may list "meat" as its first ingredient, and "corn" as its second. The manufacturer doesn't hesitate to point out that its competitor lists "corn" first ("meat meal" is second), suggesting the competitor's product has less animal-source protein than its own. However, meat is very high in moisture (approximately 75% water). On the other hand, water and fat are removed from meat meal, so it is only 10% moisture (what's left is mostly protein and minerals). If we could compare both products on a dry matter basis (mathematically "remove" the water from both ingredients), one could see that the second product had more animal-source protein from meat meal than the first product had from meat, even though the ingredient list suggests otherwise.

That is not to say that the second product has more "meat" than the first, or in fact, any meat at all. Meat meal is not meat *per se*, since most of the fat and water have been removed by rendering. Ingredients must be listed by their "common or usual" name. Most ingredients on pet food labels have a corresponding definition in the AAFCO Official Publication. For example, "meat" is defined as the "clean flesh of slaughtered mammals and is limited to...the striate muscle...with or without the accompanying and overlying fat and the portions of the skin, sinew, nerve and blood vessels which normally accompany the flesh." On the other hand, "meat meal" is "the rendered product from mammal tissues, exclusive of any added blood, hair, horn, hide trimmings, manure, stomach and rumen contents." Thus, in addition to the processing, it could also contain parts of animals one would not think of as "meat." Meat meal may not be very pleasing to think about eating yourself, even though it's probably more nutritious. Animals do not share in people's aesthetic concerns about the source and composition of their food. Regardless, the distinction must be made in the ingredient list (and in the product name). For this reason, a product containing "lamb meal" cannot be named a "Lamb Dinner."

Further down the ingredient list, the "common or usual" names become less common or usual to most consumers. The majority of ingredients with chemical-sounding names are, in fact, vitamins, minerals, or other nutrients. Other possible ingredients may include artificial colors, stabilizers, and preservatives. All should be either "Generally Recognized As Safe (GRAS)" or approved food additives for their intended uses.

If scientific data are presented that show a health risk to animals of an ingredient or additive, CVM can act to prohibit or modify its use in pet food. For example, propylene glycol was used as a humectant in soft-moist pet foods, which helps retain water and gives these products their unique texture and taste. It was affirmed Generally Recognized As Safe (GRAS) for use in human and animal food before the advent of soft-moist foods. It was known for some time that propylene glycol caused Heinz Body formation in the red blood cells of cats (small clumps of proteins seen in the cells when viewed under the microscope), but it could not be shown to cause overt anemia or other clinical effects. However, recent reports in the veterinary literature of scientifically sound studies have shown that propylene glycol reduces the red blood cell survival time, renders red blood cells more susceptible to oxidative damage, and has other adverse effects in cats consuming the substance at levels found in soft-moist food. In light of this new data, CVM amended the regulations to expressly prohibit the use of propylene glycol in cat foods.

Another pet food additive of some controversy is ethoxyquin, which was approved as a food additive over thirty-five years ago for use as an antioxidant chemical preservative in animal feeds. Approximately ten years ago, CVM began receiving reports from dog owners attributing the presence of ethoxyquin in the dog food with a myriad of adverse effects, such as allergic reactions, skin problems, major organ failure, behavior problems, and cancer. However, there was a paucity of available scientific data to support these contentions, or to show other adverse effects in dogs at levels approved for use in dog foods. More recent studies by the manufacturer of ethoxyquin showed a dose-dependent accumulation of a hemoglobin-related pigment in the liver, as well as increases in the levels of liver-related enzymes in the blood. Although these changes are due to ethoxyquin in the diet, the pigment is not made from ethoxyquin itself, and the health significance of these findings is unknown. More information on the utility of ethoxyquin is still needed in order for CVM to amend the maximum allowable level to below that which would cause these effects, but which still would be useful in preserving the food. While studies are being conducted to ascertain a more accurate minimum effective level of ethoxyquin in dog foods, CVM has asked the pet food industry to voluntarily lower the maximum level of use of ethoxyquin in dog foods from 150 ppm (0.015%) to 75 ppm. Regardless, most pet foods that contained ethoxyquin never exceeded the lower amount, even before this recommended change.

Guaranteed Analysis

At minimum, a pet food label must state guarantees for the minimum percentages of crude protein and crude fat, and the maximum percentages of crude fiber and moisture. The "crude" term refers to the specific method of testing the product, not to the quality of the nutrient itself.

Some manufacturers include guarantees for other nutrients as well. The maximum percentage of ash (the mineral component) is often guaranteed, especially on cat foods. Cat foods commonly bear guarantees for taurine and magnesium as well. For dog foods, minimum percentage levels of calcium, phosphorus, sodium, and linoleic acid are found on some products.

Guarantees are declared on an "as fed" or "as is" basis, that is, the amounts present in the product as it is found in the can or bag. This doesn't have much bearing when the guarantees of two products of similar moisture content are compared (for example, a dry dog food versus another dry dog food). However, when comparing the guaranteed analyses between dry and canned products, one will note that the levels of crude protein and most other nutrients are much lower for the canned product. This can be explained by looking at the relative moisture contents. Canned foods typically contain 75-78% moisture, whereas dry foods contain only 10-12% water. To make meaningful comparisons of nutrient levels between a canned and dry product, they should be expressed on the same moisture basis.

The most accurate means of doing this is to convert the guarantees for both products to a dry matter basis. The percentage of dry matter of the product is equal to 100% minus the percentage of moisture guaranteed on the label. A dry food is approximately 88-90% dry matter, while a canned food is only about 22-25% dry matter. To convert a nutrient guarantee to a dry matter basis, the percent guarantee should be divided by the percentage of the dry matter, then multiplied by 100. For example, a canned food guarantees 8% crude protein and 75% moisture (or 25% dry matter), while a dry food contains 27% crude protein and 10% moisture (or 90% dry matter). Which has more protein, the dry or canned? Calculating the dry matter protein of both, the canned contains 32% crude protein on a dry matter basis ($8/25 \times 100 = 32$), while the dry has only 30% on a dry matter basis ($27/90 \times 100 = 30$). Thus, although it looks like the dry has a lot more protein, when the water is counted out, the canned actually has a little more. An easier way is to remember that the amount of dry matter in the dry food is about four times the amount in a canned product. To compare guarantees between a dry and canned food, multiply the guarantees for the canned food times four first.

It is especially important to look at the moisture guarantee for canned foods, even when comparing a canned food with another canned. Under AAFCO regulations, the maximum percentage moisture content for a pet food is 78%, *except* for products labeled as a "stew," "in sauce," "in gravy," or similar terms. The extra water gives the product the qualities needed to have the appropriate texture and fluidity. Some of these exempted products have been found to contain as much as 87.5% moisture. This doesn't sound like much difference until the dry matter contents are compared. For example, a product with a guarantee of 87.5% moisture contains 12.5% dry matter, only half as much as a product with a 75% moisture guarantee (25% dry matter).

Nutritional Adequacy Statement

Any claim that a product is "complete," "balanced," "100% nutritious," or similarly suggests that a product is suitable for sole nourishment that is not, in fact, nutritionally adequate is a potentially unsafe product. For this reason, an AAFCO nutritional adequacy statement is one of the most important aspects of a dog or cat food label. A "complete and balanced" pet food must be substantiated for nutritional adequacy by one of two means.

The first method is for the pet food to contain ingredients formulated to provide levels of nutrients that meet an established profile. Presently, the AAFCO Dog or Cat Food Nutrient Profiles are used. Products substantiated by this method should include the words, "(Name of product) is formulated to meet the nutritional levels established by the AAFCO (Dog/Cat) Food Nutrient Profiles." This means the product contains the proper amount of protein, calcium, and other recognized essential nutrients needed to meet the needs of the healthy animal. The recommendations of the National Research Council (NRC) were once used as the basis for nutritional adequacy, but they are no longer considered valid for this purpose.

The alternative means of substantiating nutritional adequacy is for the product to be tested following the AAFCO Feeding Trial Protocols. This means that the product, or "lead" member of a "family" of products, has been fed to dogs or cats under strict guidelines and found to provide proper nutrition. These products should bear the nutritional adequacy statement "Animal feeding tests using AAFCO procedures substantiate that (name of product) provides complete and balanced nutrition."

Regardless of the method used, the nutritional adequacy statement will also state for which life stage(s) the product is suitable, such as "for maintenance," or "for growth." A product intended "for all life stages" meets the more stringent nutritional needs for growth and reproduction. A maintenance ration will meet the needs of an adult, non-reproducing dog or cat of normal activity, but may not be sufficient for a growing, reproducing, or hard-working animal. On the other hand, an all life stages ration can be fed for maintenance. Although the higher levels of nutrients would not be harmful to the healthy adult animal, they are not really necessary. Occasionally a product may be labeled for a more specific use or life stage, such as "senior" or for a specific size or breed. However, there is little information as to the true dietary needs of these more specific uses, and no rules governing these types of statements have been established. Thus, a "senior" diet must meet the requirements for adult maintenance, but no more. A product that does not meet either of these methods must state that "this product is intended for intermittent or supplemental feeding," except if it is conspicuously identified as a snack or treat.

Feeding Directions

Feeding directions instruct the consumer on how much product should be offered to the animal. At minimum, they should include verbiage such as "feed ___ cups per ___ pounds of body weight daily." On some small cans, this may be all the information that can fit. The feeding directions should be taken as rough guidelines, a place to start. Breed, temperament, environment, and many other factors can influence food intake. Manufacturers attempt to cover almost all contingencies by setting the directions for the most demanding. The best suggestion is to offer the prescribed amount at first, and then to

increase or cut back as needed to maintain body weight in adults or to achieve proper rate of gain in puppies and kittens. A nursing mother should be offered all the food she wants to eat. **Calorie Statement** Pet foods can vary greatly in calorie content, even among foods of the same type (dry, canned) and formulated for the same life stage. Feeding directions vary among manufacturers, too, so the number of calories delivered in a daily meal of one food may be quite different from another. The number of calories in a product roughly relates to the amount of fat, although varying levels of non-calorie-containing components, such as water and fiber, can throw this correlation off. The best way for consumers to compare products and determine how much to be fed is to know the calorie content. However, until recently, calorie statements were not allowed on pet food labels. New AAFCO regulations were developed to allow manufacturers to substantiate calorie content and include a voluntary statement.

If a calorie statement is made on the label, it must be expressed on a "kilocalories per kilogram" basis. Kilocalories are the same as the "Calories" consumers are used to seeing on food labels. A "kilogram" is a unit of metric measurement equal to 2.2 pounds. Manufacturers are also allowed to express the calories in familiar household units along with the required statement (for example, "per cup" or "per can"). Even without this additional information, however, consumers can make meaningful comparisons between products and pick the product best suited for their animals' needs. As with the guaranteed analysis, the calorie statement is made on an "as fed" basis, so corrections for moisture content must be made as described above. To roughly compare the caloric content values between a canned and a dry food, multiply the value for the canned food by four.

Other Label Claims

Many pet foods are labeled as "premium," and some now are "super premium" and even "ultra premium." Other products are touted as "gourmet" items. Products labeled as premium or gourmet are not required to contain any different or higher quality ingredients, nor are they held up to any higher nutritional standards than are any other complete and balanced products.

The term "natural" is often used on pet food labels, although that term does not have an official definition either. For the most part, "natural" can be construed as equivalent to a lack of artificial flavors, artificial colors, or artificial preservatives in the product. As mentioned above, artificial flavors are rarely employed anyway. Artificial colors are not really necessary, except to please the pet owner's eye. If used, they must be from approved sources, the same as for human foods. Especially for high-fat dry products, some form of preservative must be used to prevent rancidity. Natural-source preservatives, such as mixed tocopherols (a source of vitamin E), can be used in place of artificial preservatives. However, they may not be as effective.

"Natural" is not the same as "organic." The latter term refers to the conditions under which the plants were grown or animals were raised. There are no official rules governing the labeling of organic foods (for humans or pets) at this time, but the United States Department of Agriculture is developing regulations dictating what types of pesticides, fertilizers and other substances can be used in organic farming.

Summary

Pet owners and veterinary professionals have a right to know what they are feeding their animals. The pet food label contains a wealth of information, if one knows how to read it. Do not be swayed by the many marketing gimmicks or eye-catching claims. If there is a question about the product, contact the manufacturer or ask an appropriate regulatory agency.

EXHIBIT “V”



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#) | [FDA Centennial](#)

INFORMATION FOR CONSUMERS
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

INTERPRETING PET FOOD LABELS -- SPECIAL USE FOODS

The following consumer information is provided by David A. Dzanis, DVM, Ph.D., DACVN.

Treats and Chews

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

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

Health Claims

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

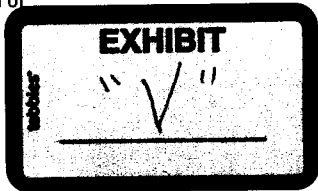
The Federal Food, Drug, and Cosmetic Act (FFDCA) defines "food" as an article used for food or drink for man or other animals. On the other hand, a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article (other than food) intended to affect the structure or function of the body of man or other animals. "Food," in the parenthetical "other than food," has been further interpreted by the courts as a substance that provides "taste, aroma, or nutritive value." If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure, or taurine for healthy heart function in cats). However, if a product affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug.

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

FDA's authority to prohibit drug claims extends beyond what is commonly considered the product "label." The FFDCA defines "labeling" as all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, brochures, flyers, signs or similar promotional material found at the point of sale may be labeling and subject to the same laws. Also, although food advertising is not regulated by the FDA, but by the Federal Trade Commission, FDA does have some authority. Advertisements or even verbal representations that establish the "intended use" of the product can be used as relevant evidence that it is a drug.

FLUTD Products

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



owners. The exact causes of FLUTD are still unclear, and a number of dietary and non-dietary factors may be involved.

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

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

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

Weight Control Products

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

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

For products that are reduced in calories but not enough to merit a "lite" claim, the rules also allow for comparative claims. For example, if a company makes a very high calorie product and a lower calorie alternative, it can still make statements such as "25% less calories than our regular product." A calorie content statement must also appear on any product bearing a calorie-based claim. In addition to "lite" and "low calorie" claims, a similar set of rules were established for "lean" and "low fat" products, except based on maximum allowable fat percentages instead of calories.

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

Dental Products

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

Skin and Coat Products

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

Perhaps most notorious is the claim for a product to be "hypoallergenic." Elimination diets are used by veterinarians in the diagnosis and management of food allergies. An elimination diet is one devoid of food ingredients likely to cause an allergy, often characterized by itchy, inflamed skin. Resolution of these clinical signs while the animal is on the diet is diagnostic of a food allergy, and trial and error then could be used to determine exactly to what the pet was allergic and what ingredients to avoid. Traditionally, lamb and rice was used as the elimination diet. There is nothing special or unique about these

ingredients in terms of allergenicity, and prolonged exposure to these ingredients could also induce an allergic condition. However, they were historically novel sources of protein, since the use of these ingredients was uncommon in commercial dog foods. As such, a pre-existing allergy to lamb or rice would be unlikely.

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

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

The same may also be true of other ingredients. For example, many fat sources may contain substances known as omega-3 fatty acids. There are some studies in the veterinary literature to suggest that when used pharmacologically, these substances may have an effect on inflammatory skin disease. However, omega-3 fatty acids are not recognized as essential nutrients at this time. In other words, dogs and cats cannot have an "omega-3 fatty acid deficiency," and unqualified claims relating to omega-3 fatty acid content may falsely imply nutritional benefit where none has been established. Thus, if a product label bears a claim for omega-3 fatty acids, it must also guarantee its level in the product, accompanied by a disclaimer that it is "not recognized as an essential nutrient by the AAFCO (Dog or Cat) Food Nutrient Profiles."

Veterinary Medical Foods

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

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

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

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

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

Dietary Supplements and "Nutraceuticals"

With the availability of today's "complete and balanced" products, nutritional supplements are needed only in very rare circumstances. Injudicious use of supplements runs a greater risk of causing dietary imbalances or toxicity than it does to actually improve the diet. Therefore, unless the pet is being fed a homemade diet that requires additional sources of certain nutrients, or unless a veterinarian diagnoses a medical condition that could benefit from supplementation, it is best not to give supplements to pets.

"Dietary supplements" describe a much broader range of products. Some provide essential nutrients, such as vitamins and minerals, but others contain substances that are not recognized as essential for the intended species (for example, vitamin C for dogs and cats, omega-3 fatty acids). Herbs, plant or organ extracts, enzymes, and a host of other substances are also

often marketed as dietary supplements. The market for dietary supplements was boosted by passage of DSHEA. This law changed the way FDA regulated these products for humans. Briefly, it said that FDA could not call a substance a "drug" or "food additive" if it met the definition for a dietary supplement and was not already regulated as a drug or food additive. Thus, it shifted the burden of the manufacturer having to prove a product was safe before it went on the market to the FDA having to prove it was unsafe before it could be removed. This prompted a sizable increase in the number and range of dietary supplements available on the market today.

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

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

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

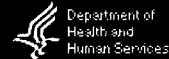
Summary

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

EXHIBIT “W”



U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#)**Guideline No. 55****SUPPORTIVE DATA FOR CAT FOOD LABELS BEARING "REDUCES URINARY PH CLAIMS: GUIDELINE IN PROTOCOL DEVELOPMENT**

Revised --

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE**Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH" Claims: Guideline in Protocol Development**

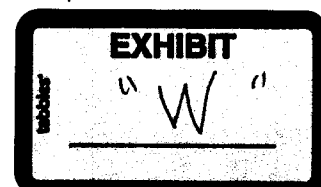
Guidelines state procedures or practices that may be useful to the persons whom they are directed, but they are not legal requirements. Guidelines represent the agency's position on a procedure or a practice at the time of their issuance. A person may follow the guideline or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent the expenditure of money or effort on activities that may later be determined to be unacceptable to FDA. A guideline does not bind the agency, and it does not confer any rights, privileges, or benefits for or on any person. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

David A. Dzanis, DVM, Ph.D., DACVN
Center for Veterinary Medicine
June, 1994

Docket No. 94D-0230

Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH" Claims: Guideline in Protocol Development

1. Test diet formulations should be nutritionally complete and balanced. This should be demonstrated by, at minimum, the successful passage of an adult maintenance feeding trial using current AAFCO protocols. Formulations should be limited to ingredients that are justifiable on a nutritional basis, and amounts of ingredients should be consistent with sound nutritional practices.
2. Product utility (i.e., the ability of the diet to produce an appropriately acidic urine) should be demonstrated by means of well controlled, scientifically sound studies. At minimum, a concurrent control group of cats fed a non-acidifying diet is needed to allow for meaningful comparisons. To facilitate data collection, cats should be housed individually, not in groups. The control diet may be a commercially available product or an experimental formulation (such as the test diet minus its acidifying components). It should also be nutritionally complete and balanced, preferably determined by previous testing using AAFCO protocols. Adequate numbers of animals in control and test groups, as determined by appropriate statistical methodology, should be used in order to be able to detect statistically significant differences between groups.
3. Data sufficient to demonstrate product safety are paramount. At minimum, data should include veterinary observations on cat health, as well as measurements of body weight, food consumption, urinalysis (including sediment examination), serum chemistries, blood gases, and mineral balances (Ca, P, Mg, K). Appropriate statistical comparisons should be conducted, using suitable methodology and numbers of animals to confidently (95 %) detect statistically significant (10%) differences, should they exist. Particular attention should be paid to parameters that assess renal and bone function. A necropsy should be performed on any animal that dies during the study, and the findings recorded. The reason for any medical treatment or removal of any animal from the study should be noted.
4. The length of the studies should be sufficient to assure product safety. At minimum, a six-month study, consistent with the length of time to conduct an AAFCO maintenance feeding trial, is needed. Food consumption and body weight determinations should be measured routinely. Data on other parameters should be collected on at least four occasions during the course of the study, including the beginning and termination of the study.
5. The submission should include all data generated, and include both data on individual animals and group summaries. Full discussion of product formulation, experimental methodology, statistical methods, and interpretation of findings should be included.
6. Data on additional parameters and/or longer studies may be required depending on the study findings. It is prudent to keep animals on test and to continue data collection while the six-month data is under review. Aliquots of serum and urine samples should be frozen for possible additional testing.



7. These key points cannot address all specifics in protocol design. Submission of protocols for review is strongly encouraged. Questions on details of the protocols should be resolved before the study is begun.

EXHIBIT “X”

 Search

Association of American Feed Control Officials

Login Register

- Home
- News and Information
- Directory
- Board Of Directors
- Order AAFCO Publications

PET FOOD RECALL NEWS!

Please visit **FDA's Center for Veterinary Medicine** for the latest news on the recent Pet Food recalls.

For additional information on regulating pet foods, [click here](#).



COMMITTEE ADVISORS

It is the general practice of AAFCO to invite representatives of industry/trade associations and consumer groups to serve as advisors to the various AAFCO committees, task forces or work groups during their open meetings. AAFCO invites these groups to nominate individuals to serve as committee advisors to be available to answer questions relevant to animal nutrition, analytical expertise, industry practices or other pertinent questions. *Committee advisors do not serve as members of an AAFCO committee, task force or work group, nor do they have a vote in any AAFCO deliberations.* The following committee advisors are currently available as a resource to the specified committee(s) or task force(s).

COLLABORATIVE CHECK SAMPLE COMMITTEE ADVISORS

- NANCY K. COOK - Pet Food Institute/Alt.
- GAIL DEGREEF - American Feed Industry Assn.
- DAVID FAIRFIELD - National Grain and Feed Assn./Alt
- ARLENE FOX - AOAC International
- JOE GARBER - National Grain and Feed Assn.
- LARS REIMAN - American Feed Industry Assn./Alt
- ROY SCHULZE - Pet Food Institute

COMMUNICATIONS COMMITTEE ADVISORS

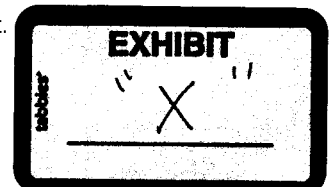
- NANCY K. COOK - Pet Food Institute/Alt.
- DAVID FAIRFIELD - National Grain and Feed Assn./Alt
- STEPHANIE GIESELLMAN - American Feed Industry Assn./Alt.
- RANDALL C. GORDON - National Grain and Feed Assn.
- KERRY KROM - American Feed Industry Assn.
- STEPHEN PAYNE - Pet Food Institute

E-COMMERCE COMMITTEE ADVISORS

- JILL FRANKS - Pet Food Institute
- RANDALL C. GORDON - National Grain and Feed Assn.
- STEPHEN PAYNE - Pet Food Institute/Alt.
- BETTY PENDLETON - American Feed Industry Assn./Alt.
- CATHY RIEFF - American Feed Industry Assn.

ENVIRONMENTAL ISSUES COMMITTEE ADVISORS

- DAVID AILOR - National Oilseed Processors Assn.
- GAIL DEGREEF - American Feed Industry Assn./Alt.



BRAD GOTTULA - National Grain and Feed Assn.
DENNIS GRIFFIN - National Renderers Assn.
JAMES HODGES, SR - American Meat Institute
MARK JENNER - American Farm Bureau Federation
CHARLOTTE KIRK BAER - National Research Council
KERRY KROM - American Feed Industry Assn.
DAVID MEEKER - National Renderers Assn./Alt.
STEPHEN PAYNE - Pet Food Institute/Alt.
JOHN PETTY - National Grain and Feed Assn./Alt.
DON WELBORN - Pet Food Institute

FEED LABELING COMMITTEE ADVISORS

JIM BARRITT - Pet Food Institute
BOB BINGHAM - Pet Food Institute/Alt.
JANET CAMPBELL - National Grain and Feed Assn.
SUE CARLSON - American Feed Industry Assn.
DAVID DZANIS - American College of Veterinary Nutrition
DAVID FAIRFIELD - National Grain and Feed Assn. Alt.
CHARLES LAMBERT - National Cattlemen's Beef Assn.
BEN MORGAN - National Cottonseed Products Assn.
KENNETH OLSON - American Farm Bureau Federation
RANDY SAMPLE - American Feed Industry Assn./Alt.
I. J. SHENKIR - American Pet Products Manufacturers Assn.
PAUL SUNDBERG - National Pork Board
GINA VALERI - American Pet Products Manufacturers Assn./Alt

FEED MANUFACTURING COMMITTEE ADVISORS

DAVID AILOR - National Oilseed Processors Assn.
BOB BROYLES - National Grain and Feed Assn./Alt.
NANCY K. COOK - Pet Food Institute/Alt.
ELIZABETH CURRY-GALVIN - American Veterinary Medical Assn.
JILL FRANKS - Pet Food Institute
BRAD GOTTULA - National Grain and Feed Assn.
KENNETH OLSON - American Farm Bureau Assn.
RANDY SAMPLE - American Feed Industry Assn./Alt.
RICHARD SELLERS - American Feed Industry Assn.
I. J. SHENIKER - American Pet Products Manufacturers Assn.
PAUL SUNDBERG - National Pork Board

INGREDIENT DEFINITIONS COMMITTEE ADVISORS

NANCY K. COOK - Pet Food Institute/Alt.
DAVID DZANIS - American College of Veterinary Nutrition
DAVID FAIRFIELD - National Grain and Feed Assn./Alt.
LARRY HENDRICKS - National Oilseed Processors Assn.
DAVID MEEKER - National Renderers Assn./Animal Protein Producers
Ind.
MICHAEL MEYERS - National Grain and Feed Assn.
JON NELSON - American Feed Industry Assn./Alt.
BETTY PENDLETON - American Feed Industry Assn.
ANGELE THOMPSON - Pet Food Institute

INSPECTION AND SAMPLING COMMITTEE ADVISORS

JANET CAMPBELL - National Grain and Feed Assn.
NANCY K. COOK - Pet Food Institute/Alt.
DAVID FAIRFIELD - National Grain and Feed Assn./Alt.
DAVID MEEKER - National Renderers Assn./Animal Protein Producers
Ind.
TED PIDDUCK - American Feed Industry Assn./Alt.
RANDY SAMPLE - American Feed Industry Assn.
STEVE WAWRZYNIAK - Pet Food Institute

LABORATORY METHODS AND SERVICES COMMITTEE ADVISORS

BRUCE ARENTSON - American Feed Industry Assn./Alt.
MARK COLEMAN - Lilly Research
DAVID FAIRFIELD - National Grain & Feed Assn./Alt
JOE GARBER - National Grain & Feed Assn.
ROB JEPPSON - Albion Advanced Nutrition
CHARLOTTE KIRK BAER - National Research Council
ANITA MISHRA - AOAC International
KENNETH OLSON - American Farm Bureau Federation
LARS REIMAN - American Feed Industry Assn.
ROY SCHULZE - Pet Food Institute

LONG RANGE PLANNING COMMITTEE ADVISORS

NANCY K. COOK - Pet Food Institute
BOB EHART - (NASDA) Washington, DC
DAVID FAIRFIELD - National Grain and Feed Assn.
RANDALL C. GORDON - National Grain and Feed Assn./Alt.
MARLENE PETERSEN - American Feed Industry Assn./Alt.
RICHARD SELLERS - American Feed Industry Assn.

MODEL BILL & REGULATIONS COMMITTEE ADVISORS

BRUCE ARENTSON - American Feed Industry Assn./Alt.
NANCY K. COOK - Pet Food Institute
DAVID DZANIS - American College of Veterinary Nutrition
BOB EHART - National Assn. of State Depts. of Agric.
RANDALL C. GORDON - National Grain and Feed Assn./Alt.
JARVIS HAUGEBOG - National Grain and Feed Assn.
MARLENE PETERSEN - American Feed Industry Assn.
I. J. SHENKIR - American Pet Products Manufacturers Assn.
GINA VALERI - American Pet Products Manufacturers Assn./Alt.
STEVE WAWRZYNIAK - Pet Food Institute/Alt.

PET FOOD COMMITTEE ADVISORS

NANCY K. COOK. - Pet Food Institute/Alt.
DAVID DZANIS - American College of Veterinary Nutrition
RUSSELL A. FREY - American Veterinary Medical Assn.
DAN HERMAN - National Fishmeal and Oil Assn.
CHARLOTTE KIRK BAER - National Research Council
SUZANNE LAVICTOIRE - Canadian Veterinary Medical Assn.
SHARON MACKLIK - American Feed Industry Assn.
RICHARD SELLERS - American Feed Industry Assn./Alt.
I.J. SHENKIR - American Pet Products Manufacturers Assn./Alt.
STEVEN SHERMAN - National Nutritional Food Assn.
ANGELE THOMPSON - Pet Food Institute
LINDA WORKMAN - American Animal Hospital Assn.
GINA VALERI - American Pet Products Manufacturers Assn.

STATES-INDUSTRY RELATIONS COMMITTEE ADVISORS

BRUCE ARENTSON - American Feed Industry Assn./Alt.
MIKE MALECHA - National Grain and Feed Assn. Alt.
DAVID MEEKER - National Renderers Assn./Animal Protein Producers
Ind.
BEN MORGAN - National Cottonseed Products Assn.
MARLENE PETERSEN - American Feed Industry Assn.

JOHN PETTY - National Grain and Feed Assn.
STEVE WAWRZYNIAK - Pet Food Institute

TSE ISSUES COMMITTEE

BRUCE ARENTSON - American Feed Industry Assn./Alt.
NANCY K COOK - Pet Food Institute
BOB EHART - (NASDA) Washington, DC
DAVID MEEKER - Natl Renderers Assn./Animal Protein Producers Ind.
JARVIS HAUGEBERG - National Grain and Feed Assn.
RANDALL C. GORDON - National Grain and Feed Assn./Alt.
RICHARD SELLERS - American Feed Industry Assn.

EXHIBIT “Y”



Search

Association of American Feed Control Officials

[Login](#) [Register](#)

- [Home](#)
- [News and Information](#)
- [Directory](#)
- [Board Of Directors](#)
- [Order AAFCO Publications](#)

PET FOOD RECALL NEWS! 

Please visit **FDA's Center for Veterinary Medicine** for the latest news on the recent Pet Food recalls.


For additional information on regulating pet foods, [click here](#).



The term **AAFCO** stands for the **Association of American Feed Control Officials**. A basic goal of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards and enforcement policies for regulating the manufacture, distribution and sale of animal feeds; resulting in safe, effective, and useful feeds. The Association thereby promotes new ideas and innovative procedures and urges their adoption by member agencies, for uniformity.

Purpose and Function of AAFCO:


The purpose of the corporation shall be to establish and maintain an Association through which officials of any state, dominion, federal or other governmental agency and employees thereof charged with a responsibility in enforcing the laws regulating the production, labeling, distribution, or sale of animal feeds or livestock remedies may unite to explore the problems encountered in administering such laws, to develop just and equitable standards, definitions and policies to be followed in enforcing such laws, to promote uniformity in such laws, regulations and enforcement policies, and to cooperate with members of the industry producing such products in order to promote the effectiveness and usefulness of such products.



Our website has been redesigned to be more user friendly and to better accommodate the needs of the association and you. We will be continuously making changes to the website, so please visit us often to track our progress.

Feel free to drop an email and let us know what you think.
Sharon@aafco.org

If you need to contact the webmaster, please click here:
walshm@purdue.edu



[Privacy Statement](#) Copyright 2007 by AAFCO

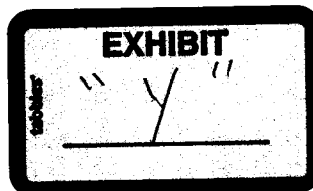


EXHIBIT “Z”



CENTER FOR VETERINARY MEDICINE

[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#) | [FDA Centennial](#)

INFORMATION FOR CONSUMERS
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

SELECTING NUTRITIOUS PET FOODS

*The following consumer information is provided by David A. Dzanis, D.V.M., Ph.D., DACVN
 Division of Animal Feeds, Center for Veterinary Medicine.*

November 1997

Most pet owners have heard that it is better to feed their animals specially formulated food for pets rather than table scraps. An occasional treat is fine, but table scraps used to excess may unbalance a pet's diet. Purchasing pet foods labeled as "complete and balanced" can help ensure that your pet's diet is nutritionally adequate.

Dog and cat foods labeled as "complete and balanced" must meet standards established by the Association of American Feed Control Officials (AAFCO) either by meeting a nutrient profile or by passing a feeding trial. The AAFCO's Canine Nutrition Expert (CNE) Subcommittee and Feline Nutrition Expert (FNE) Subcommittee have established new nutrient profiles for "complete and balanced" dog and cat foods. Dog Food Nutrient Profiles were established in 1991 and Cat Food Nutrient Profiles were established in 1992. Both were updated in 1995 to incorporate new scientific information.

The new nutrient profiles replaced the recommendations of the National Research Council (NRC) as the AAFCO-recognized authority on canine and feline nutrition. Dog and cat foods labeled as "complete and balanced" based on the AAFCO Dog or Cat Food Nutrient Profile must meet all the nutrient minimum and maximum levels as established by the Subcommittee. The Subcommittee set these levels after considering the most current information on good nutrition for dogs and cats. The profiles are designed to provide practical information for manufacturers of dog and cat foods.

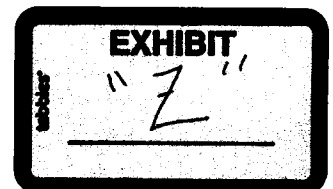
There are now two separate nutrient profiles -- one for growth and reproduction and one for adult maintenance, instead of just one for all lifestages. This allows dog and cat foods made for adult animals only to contain lower amounts of some nutrients, eliminating unnecessary excesses. Also, maximum levels of intake of some nutrients have been established for the first time, because of concern that overnutrition, rather than undernutrition, is a bigger problem with many pet foods today.

The protocols for conducting the feeding trials for dog and cat foods have also been updated. With these improvements, label reference to either the AAFCO nutrient profile or AAFCO feeding trials better assures the consumer of the validity of a "complete and balanced" claim. Endorsements, seals of approval, etc., from other organizations do not add assurances of safety and may be misleading.

Attached are tables which list the AAFCO nutritional profiles for dog and cat foods. It must be noted that the levels of nutrients are expressed on a "dry matter" basis, while the levels listed in the guaranteed analysis on the label are expressed on an "as fed" basis. To allow for meaningful comparisons, the "as fed" guarantees must be converted to "dry matter." For a canned product that is 75 percent moisture (25 percent dry matter), multiply the guaranteed level times 4. For a 10 percent moisture dry product, multiply by 1.1.

TABLE 1 -- AAFCO Dog Food Nutrient Profiles^a

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum	Maximum
Protein	%	22.0	18.0	
Arginine	%	0.62	0.51	
Histidine	%	0.22	0.18	
Isoleucine	%	0.45	0.37	
Leucine	%	0.72	0.59	
Lysine	%	0.77	0.63	
Methionine-cystine	%	0.53	0.43	



Phenylalanine-tyrosine	%	0.89	0.73	
Threonine	%	0.58	0.48	
Tryptophan	%	0.20	0.16	
Valine	%	0.48	0.39	
Fat ^b	%	8.0	5.0	
Linoleic acid	%	1.0	1.0	
Minerals				
Calcium	%	1.0	0.6	2.5
Phosphorus	%	0.8	0.5	1.6
Ca:P ratio		1:1	1:1	2:1
Potassium	%	0.6	0.6	
Sodium	%	0.3	0.06	
Chloride	%	0.45	0.09	
Magnesium	%	0.04	0.04	0.3
Iron ^c	mg/kg	80.0	80.0	3000.0
Copper ^d	mg/kg	7.3	7.3	250.0
Manganese	mg/kg	5.0	5.0	
Zinc	mg/kg	120.0	120.0	1000.0
Iodine	mg/kg	1.5	1.5	50.0
Selenium	mg/kg	0.11	0.11	2.0
Vitamins				
Vitamin A	IU/kg	5000.0	5000.0	25000.0
Vitamin D	IU/kg	500.0	500.0	5000.0
Vitamin E	IU/kg	50.0	50.0	1000.0
Thiamine ^e	mg/kg	1.0	1.0	
Riboflavin	mg/kg	2.2	2.2	
Pantothenic acid	mg/kg	10.0	10.0	
Niacin	mg/kg	11.4	11.4	
Pyridoxine	mg/kg	1.0	1.0	
Folic Acid	mg/kg	0.18	0.18	
Vitamin B12	mg/kg	0.022	0.022	
Choline	mg/kg	1200.0	1200.0	

^a Presumes an energy density of 3.5 kcal ME/g DM, based on the "modified Atwater" values of 3.5, 8.5, and 3.5 kcal/g for protein, fat, and carbohydrate (nitrogen-free extract, NFE), respectively. Rations greater than 4.0 kcal/g should be corrected for energy density; rations less than 3.5 kcal/g should *not* be corrected for energy.

^b Although a true requirement for fat per se has not been established, the minimum level was based on recognition of fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.

^c Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^d Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^e Because processing may destroy up to 90 percent of the thiamine in the diet, allowance in formulation should be made to ensure the minimum nutrient level is met after processing.

TABLE 2 -- AAFCO Cat Food Nutrient Profiles^a

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum	Maximum
Protein	%	30.0	26.0	
Arginine	%	1.25	1.04	
Histidine	%	0.31	0.31	
Isoleucine	%	0.52	0.52	
Leucine	%	1.25	1.25	
Lysine	%	1.20	0.83	
Methionine-cystine	%	1.10	1.10	
Methionine	%	0.62	0.62	1.50
Phenylalanine-tyrosine	%	0.88	0.88	
Phenylalanine	%	0.42	0.42	
Threonine	%	0.73	0.73	
Tryptophan	%	0.25	0.16	
Valine	%	0.62	0.62	
Fat ^b	%	9.0	9.0	
Linoleic acid	%	0.5	0.5	
Arachidonic acid	%	0.02	0.02	
Minerals				
Calcium	%	1.0	0.6	
Phosphorus	%	0.8	0.5	
Potassium	%	0.6	0.6	
Sodium	%	0.2	0.2	
Chloride	%	0.3	0.3	
Magnesium ^c	%	0.08	0.04	
Iron ^d	mg/kg	80.0	80.0	
Copper (extruded) ^e	mg/kg	15.0	5.0	
Copper (canned) ^e	mg/kg	5.0	5.0	
Manganese	mg/kg	7.5	7.5	
Zinc	mg/kg	75.0	75.0	2000.0
Iodine	mg/kg	0.35	0.35	
Selenium	mg/kg	0.1	0.1	
Vitamins				
Vitamin A	IU/kg	9000.0	5000.0	750000.0
Vitamin D	IU/kg	750.0	500.0	10000.0

Vitamin E ^f	IU/kg	30.0	30.0	
Vitamin K ^g	mg/kg	0.1	0.1	
Thiamine ^h	mg/kg	5.0	5.0	
Riboflavin	mg/kg	4.0	4.0	
Pantothenic acid	mg/kg	5.0	5.0	
Niacin	mg/kg	60.0	60.0	
Pyridoxine	mg/kg	4.0	4.0	
Folic Acid	mg/kg	0.8	0.8	
Biotin ⁱ	mg/kg	0.07	0.07	
Vitamin B12	mg/kg	0.02	0.02	
Choline ^j	mg/kg	2400.0	2400.0	
Taurine (extruded)	%	0.10	0.10	
Taurine (canned)	%	0.20	0.20	

^a Presumes an energy density of 4.0 kcal/g ME, based on the "modified Atwater" values of 3.5, 8.5, and 3.5 kcal/g for protein, fat, and carbohydrate (nitrogen-free extract, NFE), respectively. Rations greater than 4.5 kcal/g should be corrected for energy density; rations less than 4.0 kcal/g should *not* be corrected for energy.

^b Although a true requirement for fat per se has not been established, the minimum level was based on recognition of fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.

^c If the mean urine pH of cats fed ad libitum is not below 6.4, the risk of struvite urolithiasis increases as the magnesium content of the diet increases.

^d Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^e Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^f Add 10 IU vitamin E above minimum level per gram of fish oil per kilogram of diet.

^g Vitamin K does not need to be added unless diet contains greater than 25 percent fish on a dry matter basis.

^h Because processing may destroy up to 90 percent of the thiamine in the diet, allowance in formulation should be made to ensure the minimum nutrient level is met after processing.

ⁱ Biotin does not need to be added unless diet contains antimicrobial or antivitamin compounds.

^j Methionine may substitute choline as methyl donor at a rate of 3.75 parts for 1 part choline by weight when methionine exceeds 0.62 percent.

EXHIBIT “AA”



P.O. Box 22505, Sacramento, CA 95822 • (916) 447-3085 • info@api4animals.org • www.api4animals.org

GET THE FACTS: **What's Really in Pet Food**

Plump whole chickens, choice cuts of beef, fresh grains, and all the wholesome nutrition your dog or cat will ever need.

These are the images pet food manufacturers promulgate through the media and advertising. This is what the \$15 billion per year U.S. pet food industry wants consumers to believe they are buying when they purchase their products.

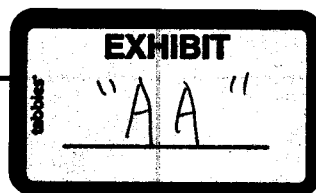
This report explores the differences between what consumers think they are buying and what they are actually getting. It focuses in very general terms on the most visible name brands — the pet food labels that are mass-distributed to supermarkets and discount stores — but there are many highly respected brands that may be guilty of the same offenses.

What most consumers don't know is that the pet food industry is an extension of the human food and agriculture industries. Pet food provides a convenient way for slaughterhouse offal, grains considered "unfit for human consumption," and similar waste products to be turned into profit. This waste includes intestines, udders, heads, hooves, and possibly diseased and cancerous animal parts.

THE PLAYERS

The pet food market has been dominated in the last few years by the acquisition of big companies by even bigger companies. With \$15 billion a year at stake in the U.S. and rapidly expanding foreign markets, it's no wonder that some are greedy for a larger piece of the pie.

- Nestlé's bought Purina to form Nestlé Purina Petcare Company (Fancy Feast, Alpo, Friskies, Mighty Dog, Dog Chow, Cat Chow, Puppy Chow, Kitten Chow, Beneful, One, ProPlan, DeliCat, HiPro, Kit'n'Kaboodle, Tender Vittles, Purina Veterinary Diets).
- Del Monte gobbled up Heinz (MeowMix, Gravy Train, Kibbles 'n Bits, Wagwells, 9Lives, Cycle, Skippy, Nature's Recipe, and pet treats Milk Bone, Pup-Peroni, Snausages, Pounce).
- MasterFoods owns Mars, Inc., which consumed Royal Canin (Pedigree, Waltham's, Cesar, Sheba, Temptations, Goodlife Recipe, Sensible Choice, Excel).



Other major pet food makers are not best known for pet care, although many of their household and personal care products do use ingredients derived from animal by-products:

- Procter and Gamble (P&G) purchased The Iams Company (Iams, Eukanuba) in 1999. P&G shortly thereafter introduced Iams into grocery stores, where it did very well.
- Colgate-Palmolive bought Hill's Science Diet (founded in 1939) in 1976 (Hill's Science Diet, Prescription Diets, Nature's Best).

Private labelers (who make food for "house" brands like Kroger and Wal-Mart) and co-packers (who produce food for other pet food makers) are also major players. Three major companies are Doane Pet Care, Diamond, and Menu Foods; they produce food for dozens of private label and brand names. Interestingly, all 3 of these companies have been involved in pet food recalls that sickened or killed many pets.

Many major pet food companies in the United States are subsidiaries of gigantic multinational corporations. From a business standpoint, pet food fits very well with companies making human products. The multinationals have increased bulk-purchasing power; those that make human food products have a captive market in which to capitalize on their waste products; and pet food divisions have a more reliable capital base and, in many cases, a convenient source of ingredients.

The Pet Food Institute — the trade association of pet food manufacturers — has acknowledged the use of by-products in pet foods as additional income for processors and farmers: "The growth of the pet food industry not only provided pet owners with better foods for their pets, but also created profitable additional markets for American farm products and for the byproducts of the meat packing, poultry, and other food industries which prepare food for human consumption."ⁱ

LABEL BASICS

There are special labeling requirements for pet food, all of which are contained in the annually revised *Official Publication* of AAFCO.ⁱⁱ While AAFCO does not regulate pet food, it does provide model regulations and standards that are followed by U.S. pet food makers.

The name of the food provides the first indication of the food's content. The use of the terms "all" or "100%" cannot be used "if the product contains more than one ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments."

The "95% Rule" applies when the ingredient(s) derived from animals, poultry, or fish constitutes at least 95% or more of the total weight of the product (or 70% excluding water for processing). Because all-meat diets are not nutritionally balanced and cause severe deficiencies if fed exclusively, they fell out of favor for many years. However, due to rising consumer interest in high quality meat products, several companies are now promoting 95% and 100% canned meats as a supplemental feeding option.

The "dinner" product is defined by the "25% Rule," which applies when "an ingredient or a combination of ingredients constitutes at least 25% of the weight of the product (excluding water sufficient for processing)", or at least 10% of the dry matter weight; and a descriptor such as "recipe," "platter," "entree," and "formula." A combination of ingredients included in the product name is permissible when each ingredient comprises at least 3% of the product weight, excluding water for processing, and the ingredient names appear in descending order by weight.