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Guidance for Industry

MANUFACTURE AND LABELING OF RAW MEAT FOODS FOR COMPANION AND CAPTIVE NONCOMPANION CARNIVORES AND OMNIVORES

Draft Guidance

This guidance document is being distributed for comment purposes only

This draft guidance is intended to provide specific guidance on the manufacture and labeling of foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores.

Comments and suggestions regarding this document should be sent to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5600 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 02D-0468. Submit electronic comments to http://www.fda.gov/dockets/comments.

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Additional copies of this draft guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855 and may be viewed on the Internet at http://www.fda.gov/cvm.

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DRAFT GUIDANCE FOR INDUSTRY

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This draft guidance represents the agency's current thinking on these products. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternate approach may be used as long as it satisfies the requirements of applicable statutes and regulations.

I. Background

Foods for carnivorous and omnivorous animals containing raw meat, or other raw animal tissues, have been on the market for many years for use by zoos, mink farms, dog racing facilities, and other professional establishments. Some of these products may have included meat and other tissues from mammals or poultry that have died other than from slaughter or have otherwise been unfit for human consumption. Products containing such tissues are adulterated under Section 402(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA). However, the Food and Drug Administration's (FDA) Compliance Policy Guide (CPG) 7126.23 stipulates that investigation should only be conducted as a follow-up to complaints or reports of injuries. When raw meat or raw animal tissues were purchased and used by zoos, mink farms, dog racing facilities, or other professional establishments, there was a presumption that the purchaser was aware of the potential risks of using such products, from both a food safety and nutritional deficiency perspective, and could take measures to mitigate those risks. However, the new trend is toward use of raw meat foods for companion and captive noncompanion animals by owners who may not be as aware of the potential for harm.

The FDA does not believe raw meat foods are consistent with the goal of protecting the public from significant health risks, particularly when such products are brought into the home and/or used to feed domestic pets. These products are foods that do not require pre-marketing approval or certification under current United States laws. Objective data derived specifically from commercial raw meat pet foods are sparse for quantifying the magnitude of risk to public health from such products. However, the potential for risk to public health from such products is undeniable, and the magnitude of such risk is likely significant given the microbiological results from studies of ingredients that could compose such products and the limited sampling of commercial raw pet foods themselves.[1-8] Therefore, for firms choosing to manufacturer and market raw meat and raw animal tissue products for animal food, more specific guidance for industry is warranted for how such products could be manufactured and labeled in order to protect pet owners and pets from risks involving food safety, nutritional deficiency, and ensure compliance with the law.

II. Considerations

Safety: It is unlawful to introduce into interstate commerce any food, including pet food, which is adulterated, (Section 301(a) of the FFDCA). Among the circumstances in which a food will be deemed adulterated are when: (a) it contains any poisonous or deleterious substance that may render it injurious to health, unless the quantity does not ordinarily render the food injurious to health; (b) it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and (c) it is, in whole or in part, the product of a diseased animal or of an animal that has died otherwise than by slaughter, (Section 402(a) of the FFDCA). These circumstances are particularly relevant to raw meat products for animals, in large part because they are not heat treated and because raw animal tissues may harbor many potentially pathogenic organisms, including bacteria (e.g., *Salmonella, Escherichia coli*) and parasites.[1-4] The FDA has promulgated a regulation specifying that meat scraps or other similar animal by-products are adulterated when they are found upon examination to be contaminated with Salmonella microorganisms, (Title 21 Code of Federal Regulations (CFR) Part 500.35). Not only are the animals consuming the product at risk of infection by organisms contained in the raw tissues, but the people handling the product are also at risk. Adequate heat treatment is the most effective and efficient means of mitigating this risk. Because some processes currently used, such as freezing or freeze-drying, do not achieve the same degree of effectiveness as heat treatment, the measures discussed and recommended below are important in reducing the risk of infection and the likelihood of the product being adulterated.

- *Source of ingredients* – There are generally three sources of animal tissues for raw meat foods for animals: meat obtained directly from human-food processing facilities; meat from animals that have died by means other than slaughter; and meat originally offered, but no longer suitable, for human consumption. All raw tissues, even those inspected by the United States Department of Agriculture (USDA) and judged acceptable for sale to people for their consumption after proper cooking, pose a risk of being contaminated with pathogenic organisms.[3,4] USDA requires safe handling instructions on raw meat products intended for human consumption as described in 9 CFR Part 317.2(l)(3) and 9 CFR Part 381.125. However, raw tissues obtained from mammals or poultry that have died other than from slaughter pose significantly increased risk of contamination with pathogenic organisms.[5,6] Even when collected from a USDA inspected slaughter facility, tissues that are typically not offered for human consumption, but instead are permitted for use in animal feed, may not be subjected to the same rigorous inspection needed to minimize the risk of contamination and disease transmission. Likewise, tissues that originally passed USDA inspection for human consumption, but that were later diverted for use in animal feeds, pose a risk for increased numbers of bacterial organisms some of which may be pathogenic.[7] To minimize risk, we recommend that only sources of animal tissue ingredients that come from a USDA inspected facility and have passed USDA inspection for human consumption should be used for manufacturing foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores. In addition, we

recommend that all other ingredients be suitable for use in animal feeds, that is, the ingredients are of an appropriate grade that qualified experts would agree they are safe for use in raw food for animals.

- *Form of Ingredients* – In addition to contamination issues, the physical form of ingredients may pose a safety concern. When bone is included in other than ground form, there is an increased risk of dental or gastrointestinal trauma.[9] To mitigate these risks, only bone in ground form should be used in foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores.

- *Manufacturing* – Meats and animal tissues intended for animals other than people are not subject to USDA inspection, except those pet foods certified by USDA under its voluntary inspection program (9 CFR Part 355). Also, while FDA has Good Manufacturing Practice (GMP) regulations in place for human foods, FDA has not promulgated GMP regulations for animal feeds. Given the safety concerns noted above, manufacturers of raw meat foods for animals should take all measures necessary to prevent adulteration. Measures that would help minimize contamination by pathogenic microorganisms and prevent the growth of pathogens could include irradiating the product after final packaging as provided for in 21 CFR Part 579, participation in the USDA's voluntary inspection program (9 CFR Part 355), and practicing GMP's such as those for human foods in 21 CFR Part 110. Development and implementation of a Hazard Analysis and Critical Control Point (HACCP) program would be an effective and rational means of fostering food safety through hazard identification and preventive controls. The desired outcome is to reduce the risk of microbial contamination or other adulteration for raw pet food products entering the home.

- *Storage and handling* – Proper transport and storage of the product by manufacturers, distributors, and retailers is necessary to prevent growth of pathogens and other microorganisms that would degrade product quality and likely adulterate the product. To best prevent growth of microorganisms, products that are not freeze-dried should be kept frozen at all times. Even when all safety precautions are taken, the risk of contamination and disease transmission is increased if the final purchaser (i.e., the pet owner or animal caretaker) does not properly handle the product after sale. This includes risk not only to the animal consuming the food, but also to the person preparing or otherwise touching the food, working surfaces, bowls, or utensils that come in contact with the food. The USDA requires that instructions for handling and preparing raw meat and poultry products intended for sale to, and consumption by, people be printed on package labels as specified in 9 CFR Part 317.2(l)(3) and 9 CFR Part 381.125. As stated in Section III, we recommend that similar instructions be on labels of raw meat foods for other animals to inform the purchaser of the risk of infection from contaminating microorganisms and how to mitigate that risk.

Nutritional adequacy – Manufacturers of products intended to be offered as the sole source of nutrition for pets should substantiate the nutritional adequacy of these products. There is significant risk of nutritional deficiency or excess when such products are improperly

formulated.[8] Calcium and phosphorus are often deficient nutrients in foods based on raw meat, and should be supplemented accordingly.[8] In addition to the risk of physical trauma or impaction, large pieces of bone may not allow for efficient digestion and absorption, possibly resulting in nutritional deficiency when bone is intended to serve as a source of dietary calcium. Essential fatty acids and some trace minerals may also be deficient. Alternatively, foods based on raw meat could be excessive in vitamin A if liver is used as a major ingredient and cause vitamin A toxicity if fed for extended periods of time.[10] Other fat soluble vitamins may be either excessive or deficient as well.[8]

Although there have been claims made that raw meat foods are superior with respect to providing adequate nutrition than other products substantiated to be complete and balanced, the FDA is not aware of scientific evidence to support such claims. The FDA has not issued regulations specifying the requirements for substantiating nutritional adequacy of sole source foods, but the Association of American Feed Control Officials (AAFCO) has developed Model Regulations for Pet Food and Specialty Pet Food. These model regulations require one of two methods be used to substantiate nutritional adequacy of foods for dogs and cats intended as the sole source of nutrients other than water. One of the methods is to have the product contain nutrients in the ranges specified in the AAFCO Dog Food Nutrient Profiles and Cat Food Nutrient Profiles for the appropriate life stage of the animal. Although these Nutrient Profiles were established on the presumption of the use of ingredients common in the manufacture of conventional canned or extruded pet foods, FDA knows of no basis to conclude that the minimum and maximum concentrations of nutrients listed in the Profiles should be altered for foods based on raw meat. Thus, under Model Regulation PF7 of the Model Regulations for Pet Food and Specialty Pet Food proposed by AAFCO, a raw meat diet intended as the sole source of nutrients for pet dogs and cats must be formulated to meet the AAFCO Dog or Cat Food Nutrient Profiles for the intended life stage(s), unless it has successfully passed the appropriate feeding trials using AAFCO protocols, which is the second method for substantiating nutritional adequacy. Raw meat foods intended as the sole, or primary, source of nutrients for captive noncompanion animals should be formulated to contain nutrient contents established by authoritative scientific review committees knowledgeable in the nutrient requirements of the specific species when such information exists and is available. In the absence of specific nutrient requirements and maximum tolerances, the AAFCO Cat Food Nutrient Profiles may be a useful reference for estimating adequate nutrient contents of foods for captive noncompanion animals.

Raw meat foods tend to be high in fat, resulting in increased caloric density. Although the foods are generally highly digestible, less total dry matter is required to supply a daily caloric need, which results in less absolute quantities of other nutrients being consumed unless the increase in caloric density is also accompanied by an increase in concentrations of other required nutrients. Thus, as directed in the profiles, it is recommended that product formulations used to substantiate nutritional adequacy be compared to the AAFCO Dog or Cat Nutrient Profiles Based on Calorie Content, not simply Profiles Based on Dry Matter.

Labeling and Claims: Raw meat foods are subject to the labeling requirements listed in 21 CFR Part 501. These include, but are not limited to, the need for an accurate ingredient declaration as specified in 21 CFR Part 501.4. In addition, states laws, many of which have

adopted or adapted the AAFCO Model Regulations for Pet Food and Specialty Pet Food, usually set forth additional labeling requirements.

- *Drug claims* – Based upon the claims made for a product, its intended use may bring it within the definition of a drug under Section 201(g)(1) of the FFDCA. An article's intended use may be shown, for example, by labeling claims, advertising matter, historical use, and by oral or written statements. It may also be shown by the circumstances under which the article is offered and used, regardless of labeling or advertising. We recommend that a manufacturer consult the CVM if it is uncertain whether a claim is acceptable for food or is a drug claim.

- *Other claims* – We recommend that comparative claims with other products be scientifically substantiated. Claims that imply the product is "USDA certified," "USDA inspected," or "human grade" must not be false or misleading.

III. Guidance for manufacturing and labeling raw meat foods for companion, and captive noncompanion carnivores and omnivores

1. Manufacture
   a. Ingredient sources
      i) All meat- and poultry-derived ingredients should be USDA/Food Safety and Inspection Service (FSIS)-inspected and passed for human consumption.
      ii) Bones and other hard materials should be ground.
      iii) All other ingredients should be suitable for use in animal feeds, that is the ingredients are of an appropriate grade that qualified experts would agree they are safe for use in raw food for animals.

   b. Manufacturing process

      Manufacturing facilities should take all measures necessary to prevent adulteration. These measures could include:
      i) irradiating the final packaged product as specified in 21 CFR Part 579,
      ii) participating in the USDA voluntary inspection program for Certified Products for Dogs, Cats, and Other Carnivora (9 CFR Part 355),
      iii) following other Good Manufacturing Practices, such as those for human foods in 21 CFR Part 110, and/or
      iv) implementing a HACCP plan.

c. Storage and transport

i) Unless freeze-dried, product should remain frozen at all times prior to use.

ii) Product should be transported and stored in a manner to avoid microbial contamination and growth.

2. Labeling

Labels must conform to all pertinent FDA regulations and statutes. In addition, it is recommended that the labels conform to all applicable Association of American Feed Control Officials (AAFCO) Model Regulations.

a. Storage and Handling Information Statements

i) It is recommended that raw frozen meat and/or poultry products for animal consumption bear a handling statement, "Keep Frozen", displayed in a prominent manner on the principal display panel.

ii) We recommend that raw frozen meat and/or poultry products for animal consumption conspicuously bear a statement under a heading "Handling Guidelines for Safe Use" on the outside of the product's immediate container, stating:

"Some raw food products may contain bacteria that could cause illness to you or the animals you are feeding if mishandled. For your protection, follow these instructions for safest use.

1. Keep frozen until ready to use.
2. Thaw in refrigerator or microwave.
3. Keep raw meat and poultry separate from other foods. Wash working surfaces, utensils (including cutting boards, preparation and feeding bowls), hands, and any other items that touch or contact raw meat or poultry.
4. Refrigerate leftovers immediately or discard."

b. Ingredients and Guarantees

i) Ingredients must be listed in descending order of predominance by weight using their common or usual names as provided in 21 CFR 501.4(a). In general, FDA has recognized the AAFCO-defined names as the common or usual name as specified in Compliance Policy Guide 7126.08, Section 665.100. Ingredients not defined by AAFCO must be declared by their common or usual names as defined under 21 CFR 501.4 and 21 CFR 102.5.

ii) States that have adopted or adapted the AAFCO Model Regulations have certain requirements regarding nutritional adequacy. Model Regulation PF7 states that dog and cat food labels must include a statement of nutritional adequacy or purpose of the product, except when the dog or cat food is clearly and conspicuously identified on the principal display panel as a "snack" or "treat." This model regulation also says the nutritional adequacy statement must consist of either a claim that is substantiated as provided for by the Model Regulation or the statement: "This product is intended for intermittent or supplemental feeding only."

iii) States that have adopted or adapted the AAFCO Model Regulations also have certain requirements regarding guarantees. Model Regulation PF4 states that a pet food or specialty pet food must list certain guarantees for crude protein, crude fat, crude fiber, and moisture. In addition, this model regulation says 1) a dog or cat food label must list other required or voluntary guarantees in the same order and units of the nutrients in the AAFCO Dog (or Cat) Food Nutrient Profiles; 2) guarantees for substances not listed in the AAFCO Dog (or Cat) Profiles, or otherwise not provided for in the Model Regulations, must be accompanied by an asterisk referring to the disclaimer "not recognized as an essential nutrient by the AAFCO Dog (or Cat) Food Nutrient Profiles;" and 3) the disclaimer must appear immediately after the last such guarantee in the same size type as the guarantees.

c. Claims

i) Based upon the claims made for a product, its intended use may bring it within the definition of a drug under Section 201(g)(1) of the FFDCA. An

article's intended use may be shown, for example, by labeling claims, advertising matter, historical use, and by oral or written statements. It may also be shown by the circumstances under which the article is offered and used, regardless of labeling or advertising. We recommend that a manufacturer consult the CVM if it is uncertain whether a claim is acceptable for food or is a drug claim.

ii) Claims that may imply the product itself has been inspected or certified by USDA or another regulatory body must not be false or misleading.

iii) Claims that the product is equivalent to food for human consumption must not be false or misleading.

iv) We recommend that comparative claims be scientifically substantiated.

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