

Guidance for FDA Staff

Compliance Policy Guide

Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases

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Food and Feed Policy Staff
Office of Policy and Risk Management
Office of Regulatory Affairs
Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857*

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**U.S. Department of Health and Human Services
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COMPLIANCE POLICY GUIDE

Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. Introduction

This document provides guidance to Food and Drug Administration (FDA) staff on how to address dog and cat food diets that are labeled and/or marketed as intended for use to diagnose, cure, mitigate, treat, or prevent diseases and are also labeled and/or marketed to provide all or most of the nutrients in support of meeting the animal's total daily nutrient requirements by serving as the pet's sole diet. Section IV below lists the factors FDA intends to consider in determining whether to exercise enforcement discretion with regard to animal drug approval requirements for dog and cat food diets that claim to treat or prevent disease. This guidance does not apply to products intended for nutritional supplementation of foods for animals and/or products marketed as dietary supplements for animals.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the agency's current thinking on various topics and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

II. Background

For more than fifty years, dog and cat food manufacturers have marketed diets identified on their labels or in labeling or other communications disseminated by or on behalf of the manufacturers ("manufacturer communications") as being intended to diagnose, cure, mitigate, treat, or prevent diseases ("treat or prevent disease"). These products are intended to provide all or most of the nutrients in support of meeting the animal's daily nutrient needs, serving as the animal's sole source of nutrients or diet other than water. By virtue of their intended use to treat or prevent disease, such products meet the statutory definition of a drug in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. 321(g)(1)(B)]. In addition, these products meet the definition of food in section 201(f) of the FD&C Act [21 U.S.C. 321(f)] because they are articles used for food for animals. Consequently, under the FD&C Act, dog and cat food products that are intended to treat or prevent disease and to provide nutrients in support

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of the animal's daily nutrient needs can be regulated as drugs (section 201(g) of the FD&C Act [21 U.S.C. 321(g)]), foods (section 201(f) of the FD&C Act [21 U.S.C. 321(f)]), or both.

Section 512(a)(1) [21 U.S.C. 360b(a)(1)] of the FD&C Act provides, in general, that new animal drugs are unsafe unless they have an approved New Animal Drug Application (NADA), an approved Abbreviated New Animal Drug Application (ANADA) under section 512 of the FD&C Act [21 U.S.C. 360(b)], a conditional approval under section 571 of the FD&C Act [21 U.S.C. 360ccc], or an index listing under section 572 of the FD&C Act [21 U.S.C. 360ccc-1] (“approved” or “index listed”).¹ Unsafe new animal drugs are adulterated within the meaning of section 501(a)(5) of the FD&C Act [21 U.S.C. 351(a)(5)], misbranded under section 502(f)(1) for lacking adequate directions for use [21 U.S.C. 352(f)(1)], and their introduction into interstate commerce is a prohibited act as specified in section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

The FD&C Act also places other requirements on the manufacture of drugs. For example, it requires that all drug manufacturers register and list drugs with FDA (section 510 of the FD&C Act [21 U.S.C. 360]). This requirement applies regardless of whether the drug at issue is approved or index listed. Drugs that are manufactured in an unregistered facility, or are not drug listed, are misbranded within the meaning of section 502(o) of the FD&C Act [21 U.S.C. 352(o)], and their introduction into interstate commerce is a prohibited act as specified in section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

In addition, section 501(a)(2)(B) of the FD&C Act [21 U.S.C. 351(a)(2)(B)] requires that any animal drug product be manufactured in accordance with current good manufacturing practices applicable to drugs. Drugs that are not manufactured in accordance with current good manufacturing practices are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act [21 U.S.C. 351(a)(2)(B)], and their introduction into interstate commerce is a prohibited act as specified in section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

At the time of this CPG issuance, most dog and cat food products that claim on their labels or in their labeling or other manufacturer communications to treat or prevent disease are not approved new animal drugs, and do not comply with drug registration and listing requirements, or with current good manufacturing practices applicable to drugs even though the products are drugs under the FD&C Act. Nevertheless, in the past, FDA generally exercised enforcement discretion with regard to these requirements for dog and cat food diets that claim to treat or prevent disease when 1) those products provided all or most of the nutrients in support of the animal's total required daily nutrient needs, 2) product labels and labeling and other manufacturer communications that were available to the general public (i.e., non-veterinary professionals) did not contain claims to treat or prevent disease, and 3) those products were distributed only through licensed veterinarians.

¹Products intended for use in dogs or cats are not eligible to be index listed new animal drugs because dogs and cats are considered major species under the FD&C Act, and index listing is limited to products for minor species.

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FDA has observed an increase in the number of dog and cat food products that manufacturers offer for use in the treatment or prevention of disease and an increase in the number of such products that are being sold directly to consumers. Because of this increase, and to help ensure animal safety, FDA is issuing this CPG to provide guidance to FDA staff with respect to factors to consider in determining whether to take regulatory action against dog and cat food products intended to be fed as the pet's sole diet and intended for use in the treatment or prevention of disease.

III. Discussion

A. Marketing Unapproved New Animal Drugs to Pet Owners

Animal health may suffer when dog and cat food diets intended to treat or prevent disease, but which are not approved as new animal drugs, are fed to pets. These products have not been evaluated by FDA for safety, efficacy, or nutritional adequacy. Many of these products affect physiological processes to extents that may not be tolerated by all animals, may not achieve effective treatment, and/or may not provide adequate daily nutrition if fed as a sole diet.

These concerns are heightened when these products are put into use by pet owners without the direction of a licensed veterinarian. When these products are marketed directly to pet owners, there is a greater potential for product misuse and/or misunderstanding of the role of the product in the disease treatment. These products are commonly labeled or marketed for use in dogs or cats with diseases or conditions that cannot be accurately diagnosed by pet owners. In addition, the labeling or other materials may lack sufficient information, particularly for pet owners, on the effectiveness, possible side effects, and contraindications for use. For example, owners of diabetic dogs and cats may misinterpret claims to "control blood glucose" to represent that the product is the sole treatment required for diabetic dogs and cats when, in fact, these animals may require insulin therapy or other treatments to adequately control blood glucose. Also, some dog and cat food diets intended to treat obesity may not be formulated to meet daily requirements for nutrients other than calories, which pet owners may not understand without guidance from a veterinary professional.

These concerns are reduced when such dog and cat food diets are marketed only through and used under the direction of a licensed veterinarian. Veterinarians typically discuss an animal's nutritional needs with the pet owner, make periodic assessments of the animal's health, and provide direction to the pet owner for how to use the product. Veterinarians can also help ensure that animals diagnosed as suffering from a disease or other health condition receive other appropriate treatments for their condition. Because these products have not been evaluated for safety and efficacy, veterinary oversight is especially important to provide periodic assessment of how the animal is reacting to the diet and to discontinue the product's use when warranted. Accordingly, one of the factors FDA will consider in exercising enforcement discretion is whether the product is made available to the public exclusively through licensed veterinarians or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian.

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FDA will consider whether the product is responsibly marketed in other respects as well. For example, a therapeutic claim that is not scientifically substantiated would be considered false or misleading, thus making the product misbranded. FDA does not intend to exercise enforcement discretion when such products present a known safety risk (e.g., when a product labeled for use in dogs or cats with a particular disease would be unsafe in such animals) or if the labeling of the product or other manufacturer communications regarding the product contain false or misleading claims (e.g., dog food labeled and promoted for the treatment of cancer with no basis for the claim). See Compliance Policy Guide, Sec. 120.500: Health Fraud - Factors in Considering Regulatory Action. FDA also does not intend to exercise enforcement discretion when a product is marketed as an alternative to approved new animal drugs.

B. Animal Food Ingredients

Ingredients added to food must be either approved food additives or generally recognized as safe (GRAS) for their intended use in food. Title 21, Code of Federal Regulations, section 570.30 [21 C.F.R. 570.30] sets out the eligibility for classification of food ingredients to be GRAS. A partial listing of substances that are GRAS for an intended use in animal food appears in 21 C.F.R. 582 and 584; 21 C.F.R. 573 contains approved food additives permitted in animal food. Section 409 of the FD&C Act [21 U.S.C. 348] provides that food additives are unsafe unless they are the subject of a food additive regulation prescribing the conditions under which the food additive may be safely used [21 C.F.R. 573]. In addition, section 402(a)(2)(C) of the FD&C Act [21 U.S.C. 342(a)(2)(C)] deems foods that contain an unapproved food additive to be adulterated.

FDA does not generally intend to recommend or initiate regulatory actions against food products containing unapproved food additives if those unapproved food additives are included as a food ingredient definition in the 2015 *Official Publication* of the Association of American Feed Control Officials (AAFCO), unless there are data indicating that safety or suitability issues exist with an AAFCO defined ingredient.²

IV. Enforcement Policy

Under section 201(g)(1)(B) of the FD&C Act, dog and cat food products that are intended to treat or prevent disease are drugs, even if they also provide nutrients in support of the animal's total required daily nutrient needs.

Unless these products are approved as new animal drugs, these products are adulterated under section 501(a)(5) and misbranded under 502(f)(1) of the FD&C Act. In addition, in the absence of compliance with current good manufacturing practice requirements, these products are adulterated under section 501(a)(2)(B) of the FD&C Act. Unless these products are

²Although food containing these unapproved food additives is adulterated within the meaning of section 402(a)(2)(c)(i), FDA is unlikely to initiate enforcement action solely on this basis if the food additive in question is included in the 2015 edition of the *Official Publication* of the Association of American Feed Control Officials. As part of its efforts to work with State partners, FDA has reviewed safety information related to many of these listed products, and those listed in the 2015 *Official Publication* generally do not fall within our current enforcement priorities.

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manufactured in and listed by a facility that is registered under section 510 of the FD&C Act, they are misbranded under section 502(o) of the FD&C Act. However, FDA is less likely to initiate enforcement action against dog and cat food products intended to be fed as the pet's sole diet that claim to treat or prevent disease when all of the following factors are present:

1. The product is made available to the public only through licensed veterinarians or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian.
2. The product does not present a known safety risk when used as labeled (e.g., when a product labeled for use in dogs or cats with a particular disease would be unsafe in such animals).
3. The product *label* does not include representations that it can be used to treat or prevent disease (e.g., obesity, renal failure).
4. Distribution of labeling and other manufacturer communications that contain representations that the product is intended for treatment or prevention of disease is limited so that it is provided only to veterinary professionals.
5. Electronic resources for the dissemination of labeling information and other manufacturer communications related to the intended use of the product are secured so that they are available only to veterinary professionals.
6. The label and labeling of the product is not false or misleading in other respects (e.g., dog food labeled and promoted for the treatment of cancer with no basis for the claim).
7. The product is not marketed as an alternative to approved new animal drugs.
8. The manufacturer is registered under section 415 of the FD&C Act.
9. The product is manufactured in accordance with CGMPs applicable to animal food (see 21 CFR part 507 subpart B)³ and other regulations applicable to animal food manufacturing.
10. The product's labeling complies with all food labeling requirements for such products (see 21 CFR part 501).
11. The product contains only ingredients that are GRAS ingredients, approved food additives, or ingredients defined in the 2015 *Official Publication* of the Association of American Feed Control Officials.

³Compliance with 21 CFR part 507, subpart B, begins on September 19, 2016, for certain animal food facilities. Other facilities are required to comply on September 18, 2017, and September 17, 2018. For more information on these compliance dates, see the preamble for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (80 FR 56170 at 56328-30).

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V. Regulatory Action Guidance

Districts should consult with the CVM, Division of Compliance, Post-Market Compliance Team (HFV-232) prior to taking regulatory action against dog and cat food products intended to be fed as the pet's sole diet and intended for use to treat or prevent disease.

Districts should consider enforcement action against a product when one or more of the factors listed in Section IV of this CPG are not present.