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Draft Compliance Policy Guide

LABELING AND MARKETING OF NUTRITIONAL PRODUCTS INTENDED FOR USE TO DIAGNOSE, CURE, MITIGATE, TREAT, OR PREVENT DISEASES IN DOGS AND CATS

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
and
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DRAFT COMPLIANCE POLICY GUIDE

LABELING AND MARKETING OF NUTRITIONAL PRODUCTS INTENDED TO DIAGNOSE, CURE, MITIGATE, TREAT, OR PREVENT DISEASES IN DOGS AND CATS

This draft Compliance Policy Guide, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if such approach satisfies the requirements of the applicable statute and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this Compliance Policy Guide. If you cannot identify the appropriate FDA staff, call the number listed on the title page of this guidance.

I. Introduction

This document provides guidance to the Food and Drug Administration (FDA) staff on how FDA intends to address dog and cat food products that are labeled and/or marketed as intended for use to diagnose, cure, mitigate, treat, or prevent diseases and are labeled and marketed to provide nutrients in support of meeting the animal's total daily nutrient requirements.

FDA's guidance documents, including this CPG, 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 guidance documents means that something is suggested or recommended, but not required.

II. Background

For more than fifty years, dog and cat food manufacturers have marketed products identified on their labels or in labeling as being intended for use to diagnose, cure, mitigate, treat, or prevent diseases. These products also provide nutrients in support of the animal's daily nutrient needs, often serving as the animal's sole source of nutrients other than water. By virtue of their intended use to diagnose, cure, mitigate, 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 for use to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support 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]. 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)], 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 the subject of an approved NADA, an approved ANADA, a conditional approval or an index listing. 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 to diagnose, cure, mitigate, treat, or prevent diseases are not the subject of an approved NADA, an approved ANADA, a conditional approval, or an index listing, and do not currently comply with drug registration and listing requirements, or with current good manufacturing practices applicable to drugs even though the products' status are drugs under the FD&C Act (see also FDA's Center for Veterinary Medicine (CVM) Program Policy and Procedures Manual Guide 1240.3605). Nevertheless, in the past, FDA generally exercised enforcement discretion with regard to these requirements for dog and cat food products that claim to diagnose, cure, mitigate, treat, or prevent diseases, when 1) those products provide nutrients in support of the animal’s total required daily nutrient needs, 2) when manufacturers restricted label and labeling claims, and 3) distributed the products only through licensed veterinarians.

FDA has observed an increase in the number of dog and cat food products with labels and labeling that offer products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. Because of this increase, and to help ensure animal safety, FDA is issuing this draft CPG to provide guidance on its current thinking with respect to factors it will consider

in determining whether to take regulatory action against manufacturers of dog and cat food products intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases.[1]

III. Discussion

A. Appropriate Use of Product

When dog and cat food products intended for use to diagnose, cure, mitigate, treat, or prevent diseases were first marketed, they were sold through, and used under the direction of, licensed veterinarians. Recently, FDA has observed an increase in the marketing of such products directly to pet owners, including the availability of such products over the internet and in supermarkets or pet stores. This shift in marketing directly to pet owners is of concern because many of these products affect physiological processes to extents that may not be tolerated by all animals and/or may not achieve effective treatment.

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 products intended to treat obesity may not be formulated to meet daily requirements for nutrients other than calories. FDA is less concerned when such dog and cat food products are marketed only through and used under the direction of a licensed veterinarian because the agency presumes the veterinarian will provide direction to the pet owner for how to use the product including periodic assessment of the product's effectiveness in both treatment outcome and provision of adequate nutrition for the animal.

B. Availability of Product Labeling to the General Public

Animal health may suffer when dog and cat food products intended for use to diagnose, cure, mitigate, treat, or prevent disease, but which are not the subject of an approved NADA, an approved ANADA, a conditional approval or an index listing are fed to pets without sufficient oversight by a licensed veterinarian. These products have not been evaluated by FDA for safety, efficacy, or nutritional adequacy. FDA is concerned when product labels and labeling, as well as other promotional materials, indicating an intent to use the product to diagnose, cure, mitigate, treat, or prevent diseases are directly available to the general public. FDA is concerned that listing a disease or symptom on the label of a product does not provide a pet owner with sufficient information on the effectiveness, possible side effects, and contraindications for use of the product, and that, in the absence of a valid veterinarian-client-patient relationship, pet owners may misuse such a product, resulting in harm to their pets. For example, some of these products work through manipulation of physiological processes and functions that may not be tolerated by

[1] Notwithstanding the factors discussed in this guidance, FDA intends to initiate regulatory or enforcement action against products covered by the guidance when such products present a 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 products' labeling or promotion constitutes consumer health fraud (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 (CPG 7150.10).

all animals and that require veterinary oversight in order to appropriately evaluate the animal's response.

C. Feed Ingredients

Ingredients added to food must be either approved food additives or generally recognized as safe (GRAS) for their intended use in feed. Title 21, Code of Federal Regulations, section 570.30 [21 C.F.R. 570.30] sets out the eligibility for classification of feed ingredients to be GRAS. A partial listing of substances 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 feed. 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 feed products that contain unapproved food additives if those unapproved food additives are included as a feed ingredient definition in the 2012 *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]

D. Drug Listing and Manufacturer Registration

As noted, section 510 of the FD&C Act [21 U.S.C. 360] requires all drug manufacturers to register and list drugs with FDA. This requirement applies regardless of whether the drug at issue is the subject of an approved NADA, an approved ANADA, a conditional approval or an index listing. Registration and drug listing are an important part of the regulatory framework, however, since firms producing products that provide nutrition (food) are required to register under section 415 of the FD&C Act [21 U.S.C. 350d] FDA has determined that registration under section 415 of the FD&C Act is sufficient to enable FDA to carryout its regulatory requirements. Therefore, this guidance sets out an intention to exercise enforcement discretion with respect to violations of the requirements of section 510 of the FD&C Act provided the firm is registered under section 415 of the FD&C Act.

IV. Enforcement Policy

Under section 201(g)(1)(B) of the FD&C Act [21 U.S.C. 321(g)(1)(B)], dog and cat food products that are intended for use to diagnose, cure, mitigate, treat, or prevent diseases are drugs, even if they also provide nutrients in support of the animal's total required daily nutrient needs.

[2] Although 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 2012 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 2012 *Official Publication* generally do not fall within our current enforcement priorities.

Unless the subject of an approved NADA, an approved ANADA, a conditional approval, or an index listing, these products are adulterated under section 501(a)(5) of the FD&C Act [21 U.S.C. 351(a)(5)]. 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 [21 U.S.C. 351(a)(2)(B)]. However, FDA is more concerned about certain products, and thus, is less likely to initiate enforcement action against dog and cat food products that claim to diagnose, cure, mitigate, treat, or prevent diseases 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 is not marketed as an alternative to approved new animal drugs.

3. The manufacturer is register under section 415 of the FD&C Act

4. The product's labeling complies with all food labeling requirements for such products (see 21 CFR Part 501).

5. The product does not include indications for a disease claim (e.g., obesity, renal failure) on the label.

6. Distribution of labeling and promotional materials with any disease claims for the product is limited so that it is provided only to veterinary professionals.

7. Electronic resources for the dissemination of labeling information and promotional materials are secured so that they are available only to veterinary professionals.

8. The product contains only ingredients that are GRAS ingredients, approved food additives, or feed ingredients defined in the 2012 *Official Publication* of the Association of American Feed Control Officials.[2]

9. The label and labeling of the product is not false and misleading in other respects.[3]

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 that claim to diagnose, cure, mitigate, treat, or prevent diseases.

Priority for enforcement attention should be given to products that:

1. Are marketed as alternatives to approved new animal drugs.

[3] A therapeutic claim that is not scientifically substantiated would be considered false or misleading, thus making the product misbranded.

2. Contain unapproved food additives, unless the use of that unapproved food additive conforms to uses as listed in the 2012 *Official Publication* of the Association of American Feed Control Officials.

3. Include words or vignettes on the label of the product(s) that explicitly or implicitly indicate diseases for which the product is to be used.

4. Are made directly available to the public circumventing the role of a licensed veterinarian for provision of directions for use, supervision of treatment and evaluation of the treatment outcome.