Citizen Petition 7/21/2022

The undersigned submits this petition under Title 21, Chapter 1, Subpart E, Part 502, Title 21, Chapter 1, Subpart E, Part 501, and CFR 10.30 to request the Commissioner of Food and Drugs to amend the common and usual names of pet food ingredients.

A. Action Requested

We request the FDA require pet food label disclosure of feed grade ingredients as 'Feed Grade' within the ingredient panel such as:

Ingredients: Feed Grade Chicken, Feed Grade Beef...

Should a pet food/treat product consist of 100% feed grade ingredients, we ask FDA to require the label to prominently display the words 'Feed Grade' directly below the name of the product on the principal display panel and in the ingredient panel such as:

ABC Dog Food Feed Grade

Feed Grade Ingredients: Chicken, Beef...

We request the same Feed Grade disclosure to be required on pet food company websites and any promotional/advertising materials including but not limited to television advertising.

We request label claims such as "Made with Real Chicken" or "Made with Real Beef" only be allowed if the claimed ingredient conforms to the standards established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture.

Existing law: Title 21, Chapter 1, Subchapter E, Part 502.5 General Principles (a).

"The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods."

Proposed: Title 21, Chapter 1, Subchapter E, Part 502.5 General Principles (a) (1).

<u>Feed grade is a subclass and shall be declared on the label in accordance with other parts of this subchapter.</u>

Existing law: 501.4 Animal food; designation of ingredients.

"(a) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this part 501, except those exempted by § 501.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 501.2."

Proposed: 501.4 Animal food; designation of ingredients.

(a) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this part 501, except those exempted by § 501.100, shall be listed by common or usual name <u>including designation of subclass (feed grade)</u> in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 501.2.

(i) Should all animal food ingredients be of subclass feed grade, ingredients can be declared by designation 'Feed Grade Ingredients:...' in accordance with the provisions of 501.4 (a).

Existing law: 501.3 Identity labeling of animal food in package form.

- "(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.
- (e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food...
 - (f) A label may be required to bear the percentage(s) of a characterizing ingredient..."

Proposed: 501.3 Identity labeling of animal food in package form.

- (d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.
- (e) When the animal food consists of 100% subclass feed grade ingredients, the statement of identity shall be followed by "Feed Grade" presented just below the statement of identity in accordance with provisions of (d) in this section.
- (f) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food...
- (g) Under the provisions of section 403(a) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is a subclass of another food unless its label bears, in type of uniform size and prominence, declaration of the subclass (e.g. feed grade) and, immediately thereafter, the name of the food, in clear terms distinguishing it from other foods.
 - (h) A label may be required to bear the percentage(s) of a characterizing ingredient...

Existing law: 501.2 Information panel of package for animal food.

- "(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.
 - (f) If the label of..."

Proposed: 501.2 Information panel of package for animal food.

- (e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.
- (f) All information appearing on the information panel, such as product claims, shall accurately and truthfully describe the product and/or ingredients (including declaration of subclass feed grade ingredients).
 - (g) If the label of...

We ask that FDA issue a press release within 30 days alerting the public and industry of these requirements and fully implement into regulation within twelve months.

B. Grounds

1. Title 21, Chapter 9 Federal Food, Drug and Cosmetic Act, Subchapter IV Food, Section 341 Definitions and standards for food states:

"In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label."

We contend pet food feed grade ingredients are "permitted optional ingredients" (permitted through FDA enforcement discretion, optional as they do not conform to food legal standards) thus needing to be designated on pet food labels.

2. Title 21, Chapter I, Subpart E, Part 501.3 Identity Labeling of Animal Food in Packaged Form (e) states:

"Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word imitation and, immediately thereafter, the name of the food imitated.

- (1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.
- (3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation and may, in addition, bear a fanciful name which is not false or misleading, and established pursuant to part 502 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.
 - (4) Nutritional inferiority includes:
 - (i) Any reduction in the content of an essential nutrient that is present in a measurable amount.
 - (ii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food."

We contend that feed grade ingredients are "a substitute for and resembles another food but is inferior to the food imitated". We contend that feed grade ingredients are a food for which a common or usual name has not been established by regulation, confirming they are an imitation.

Example: the definition of the pet food ingredient "chicken" accepted by FDA is "Poultry is the clean combination of flesh and skin with or without accompanying bone, derived from the parts of whole carcasses of slaughtered poultry, or a combination thereof, exclusive of feathers, heads, feet, and viscera. If it bears a name descriptive of its kind, it must correspond thereto. If the bone has been removed, the process may be so designed by use of the appropriate feed term. It shall be suitable for use in animal food."

This FDA accepted definition of pet food ingredient chicken has not been established by regulation. Further this FDA accepted definition does not include the requirement to conform to standard established pursuant to the Poultry Products Inspection Act by the U.S. Department of Agriculture. Thus, the pet food feed grade ingredient chicken - per legal foundation - resembles another food but is inferior to the food imitated.

The same inferior food substitute applies to all other feed grade pet food ingredient definitions currently accepted by FDA. The same common or usual name of all other pet food ingredients have not been established by regulation.

3. Title 21, Chapter I, Subpart E, Part 502 Common or Usual Names for Nonstandardized Animal Foods states (bold added for emphasis):

"General Principles (a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods."

This legal requirement could not be more clear, animal food (pet food) ingredient names "may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name." And "each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods."

Using the same example as above, the feed grade pet food ingredient 'chicken' which does not conform to the Poultry Products Inspection Act holds the same common or usual name as 'chicken' that does conform to the Poultry Products Inspection Act - thus it is "confusingly similar" to another food. Legal foundation requires it to be given its own common or usual name that distinguishes it from different foods.

The same lack of distinction between food ingredients and feed ingredients of the same name applies to all other feed grade pet food ingredients, thus requiring them to be given their own common or usual name that states in clear terms what it is that distinguishes it from different foods.

4. FDA currently provides the private organization AAFCO the authority to define pet food ingredients through a non-binding compliance policy.

CPG Sec. 665.100 Common or Usual Names for Animal Feed Ingredients

POLICY: "The definitions, as they appear in the Official Publication of the Association of American Feed Control Officials, Inc. (AAFCO), are generally regarded as constituting the common or usual name for animal feed ingredients, including pet food, as contemplated by 403(i)(1) and (2)."

Section 403 (i)(1) and (2) as cited in the compliance policy references the Federal Food Drug and Cosmetic Act section "Misbranded foods". Section 403 specifically is titled "(i) Label where no representation as to definition and standard of identity" indicating FDA acknowledgement that pet food ingredients are nonstandardized foods, having no definition or standard of identity/are NOT similar to the same named ingredient in 'food', thus the need to rely on AAFCO definitions.

As well, by having a need for AAFCO to define pet food ingredients is evidence pet food ingredients are optional ingredients or nonstandardized ingredients.

Compliance Policy Guide 665.100 also states (bold added for emphasis): "AAFCO annually publishes its Official Publication, a handbook which contains, among other things, Official Feed Terms, which define many of the terms commonly used in the feed manufacturing industry. It also contains Official and Tentative Definitions of Feed Ingredients, a codified set of definitions for ingredients commonly used in animal feed."

We contend this section of the FDA Policy confirms existing pet food ingredient names and definitions are feed grade; "feed terms", "feed manufacturing industry", "feed ingredients", and "animal feed".

On a side note, the above quote of the Compliance Policy states AAFCO ingredients are "codified".

Cornell law school states: "To codify means to arrange laws or rules into a systematic code. The process of codification can involve taking judicial decisions or legislative acts and turning them into codified law. This process does not necessarily create new law, it merely arranges existing law, usually by subject, into a code."

The common or usual names for animal feed ingredients and definitions produced through AAFCO are not law. They are adopted into state law in some U.S. states, however as published in the AAFCO Official Publication they are not law thus not codified. The Compliance Policy Guide clearly states "AAFCO *has no legal mandate.*"

5. Section 501.110 Animal feed labeling; collective names for feed ingredients states:

"Each collective name referred to in this paragraph may be used for the purpose of labeling where one or more of the ingredients listed for that collective name are present. The animal feed ingredients listed under each of the collective names are the products defined by the Association of American Feed Control Officials. The collective names are as follows:

- (1) Animal protein products include one or more of the following: Animal products, marine products, and milk products.
- (2) Forage products include one or more of the following: Alfalfa meals, entire plant meals, hays, and stem meals
- (3) Grain products include one or more of the following: Barley, grain sorghums, maize (corn), oats, rice, rye, and wheat.

- (4) Plant protein products include one or more of the following: Algae meals, coconut meals (copra), cottonseed meals, guar meal, linseed meals, peanut meals, safflower meals, soybean meals, sunflower meals, and yeasts.
- (5) Processed grain byproducts include one or more of the following: Brans, brewers dried grains, distillers grains, distillers solubles, flours, germ meals, gluten feeds, gluten meals, grits, groats, hominy feeds, malt sprouts, middlings, pearled, polishings, shorts, and wheat mill run.
 - (6) Roughage products include one or more of the following: Cobs, hulls, husks, pulps, and straws."

Again, this section of law evidences AAFCO definitions are feed definitions; "animal feed ingredients". Feed ingredients are optional ingredients/a subclass of food that is required to be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

6. Title 21, Chapter I, Subpart E, Part 501.18 states:

"Misbranding of animal food.

(b) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic."

As we have evidenced, existing (feed grade) common or usual pet food ingredient names of the same name as food grade ingredients without disclosure are misbranded.

- Title 21, Chapter 9 Federal Food, Drug, and Cosmetic Act, Subchapter 3, Section 331 Prohibited acts states: "The following acts and the causing thereof are prohibited:
- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

Existing (feed grade) common or usual pet food ingredient names are prohibited.

C. Environmental Impact

We are unaware of any environmental impacts from our request.

D. Economic Impact

We are unaware of any economic impacts from our request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Susan Thixton Digital Signature

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