

# PETFOOD



## ESSENTIALS

Pet treats on the rise: What's new, what's next

**April 29 , 2024**

Kansas City, Missouri, USA

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# **Pet Treats and Supplements: Key differences, opportunities for synergy**

Bill Bookout, President,  
National Animal Supplement Council

11:00am – 12:15pm

29 April 2024

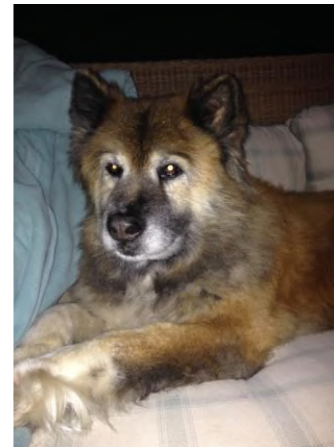
# Goals for Today's Presentation:



1. Interactive - I am sure you hear enough speakers from podiums, if you have a question, raise your hand and ask ...
2. Educational – come away knowing something you did not know before you attended
3. Know the Risks so you can make an informed business decision
4. Focus on What You CAN Do, Not just What You CAN'T Do

# Brief Overview of NASC

- NASC (the National Animal Supplement Council):
  - Non-profit industry trade association
  - Founded in 2001 due to no category for products similar to Human Dietary Supplements marketed for animals
  - Our Scope: Health Supplements and / or Nutritional Supplements
  - Non-Human Food Chain Animals (primarily Dogs, Cats, Horses)
  - Do not cover Complete and Balanced Diets



# Why Was I Asked to Speak on This Topic?

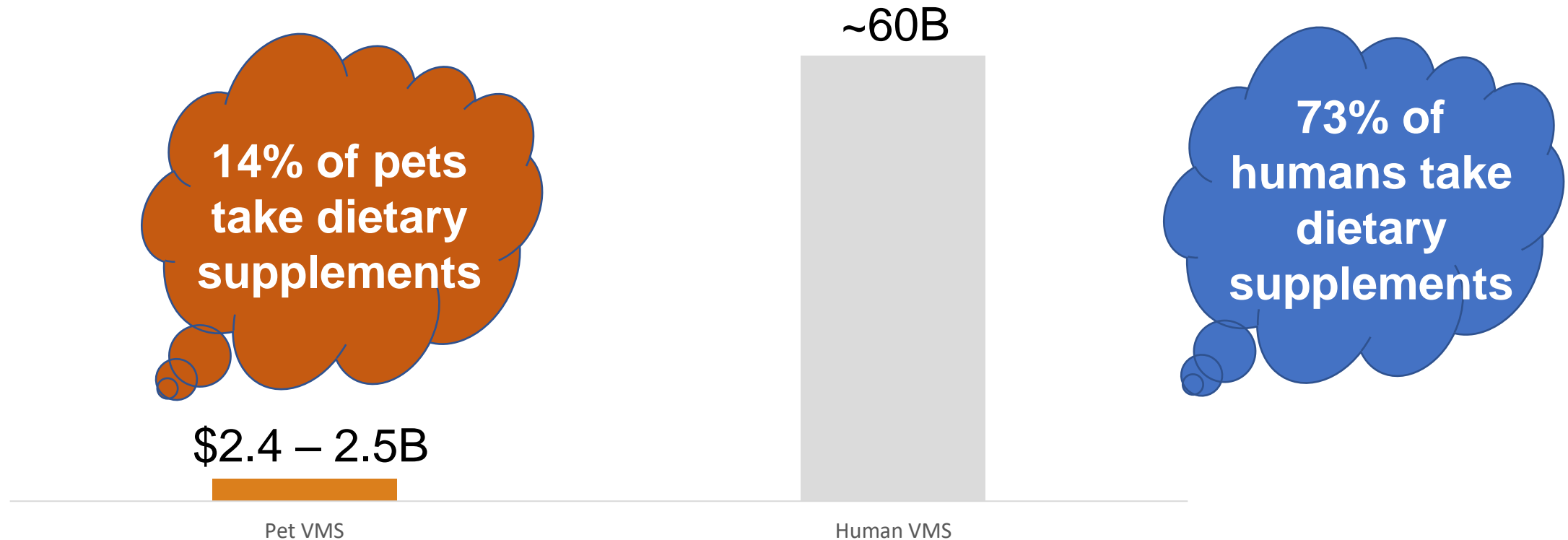
- My background (beyond the Bio):
  - Executive in the Human Medical Device / Drug Industry
    - ❖ What I am and what I am not
  - Made a career change in the mid 1990s ... had dogs with issues
  - Was CEO for the 3<sup>rd</sup> largest companion animal referral hospital in the US for 3 years
  - Started my own “supplement” company in 1999, and
- I MADE EVERY MISTAKE YOU CAN POSSIBLY MAKE ...





# Pet Supplement Market Opportunity

U.S. Pet and Human VMS Market Sizes, 2021

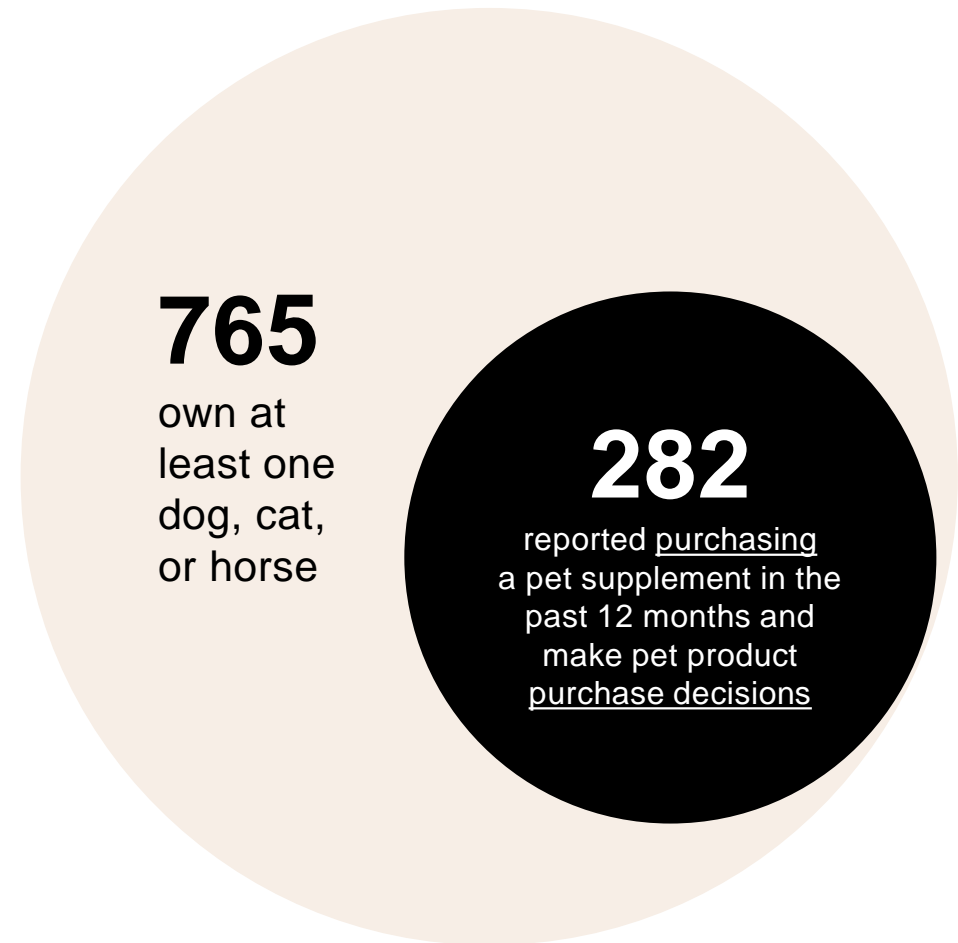


# Market Research Driving Demand

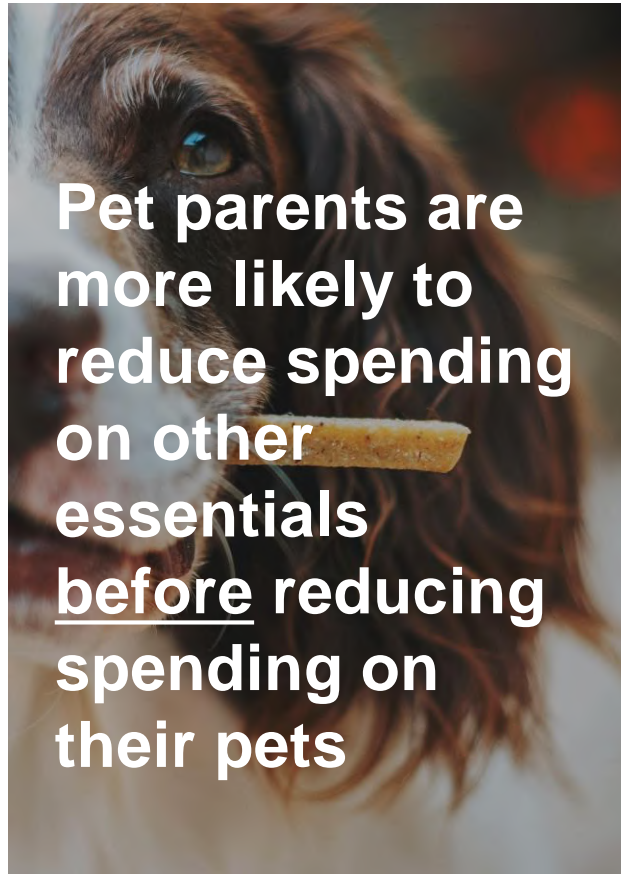
## Grounded in Research, Informed by Experience

MarketPlace conducts  
an annual survey of  
U.S. pet parents.

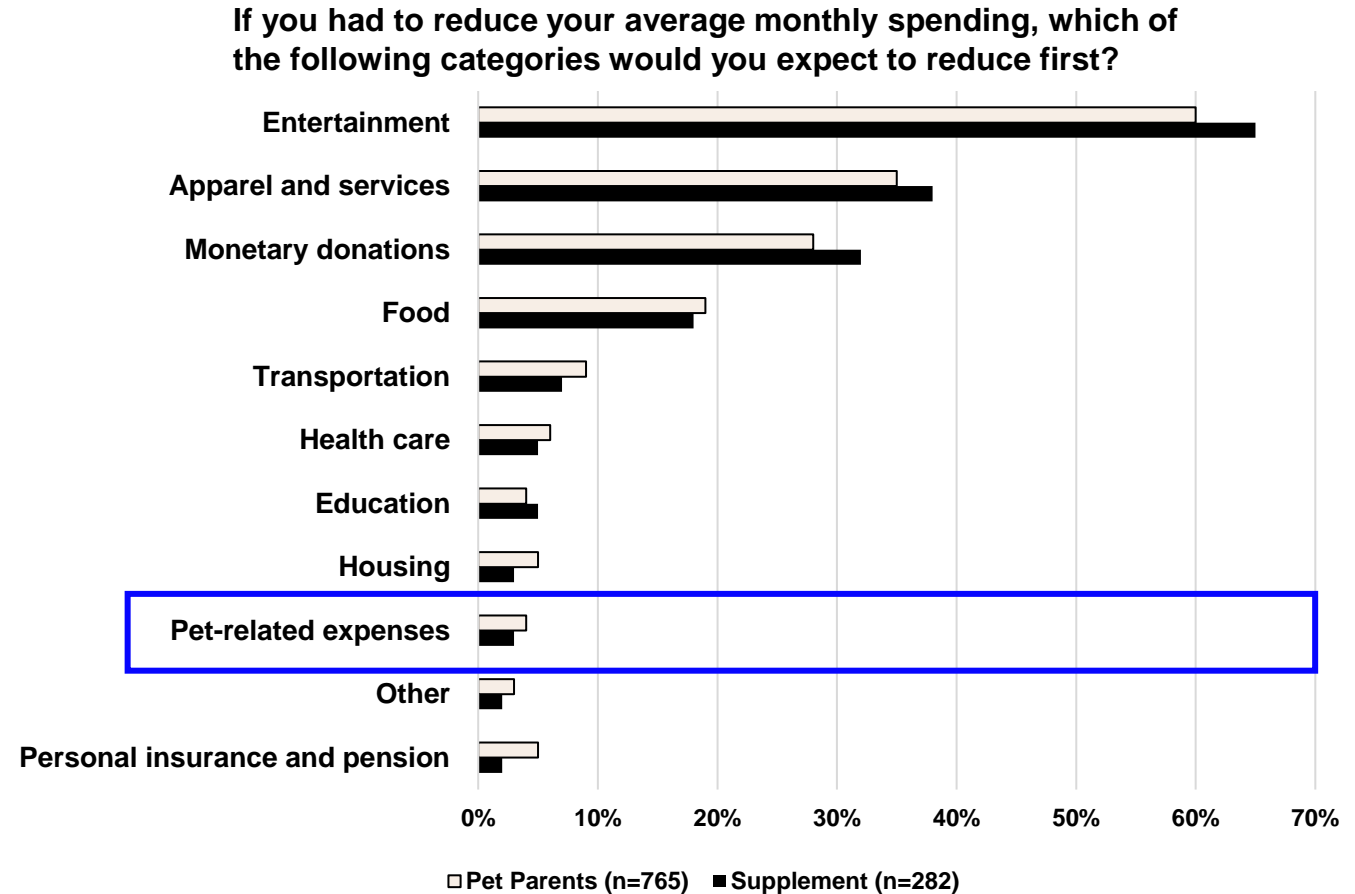
These are the results  
from 2023 research.



# Resilient Industry



Respondents were allowed to select up to two.



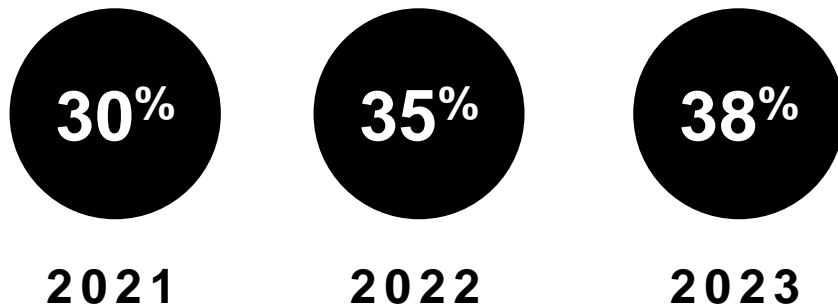
Source: 2023 Pet Parent Survey, marketplacebranding.com



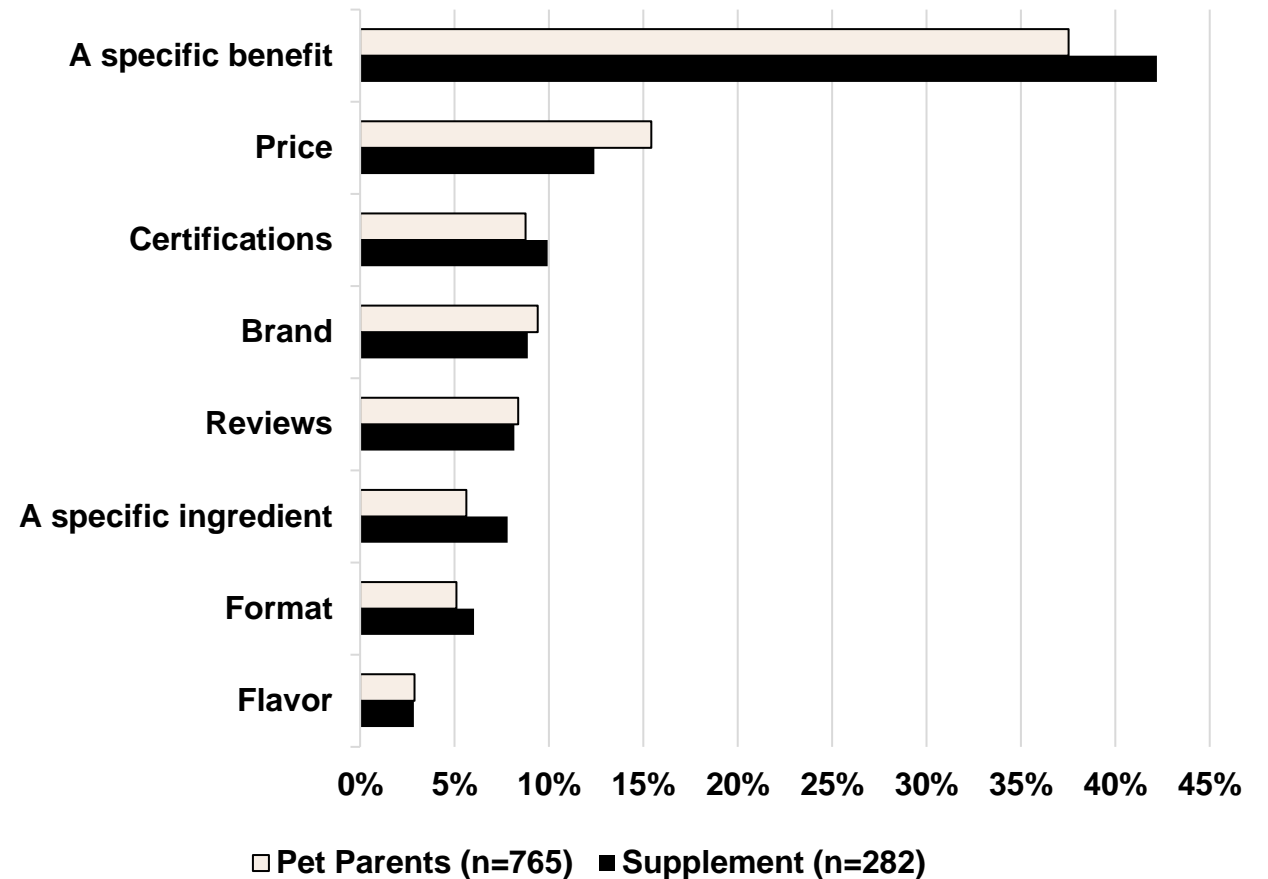
# Demand Drivers

## Consideration Begins with Benefits

% PET PARENTS WHO LOOK FIRST TO BENEFITS



PET PARENTS FIRST LOOK FOR:



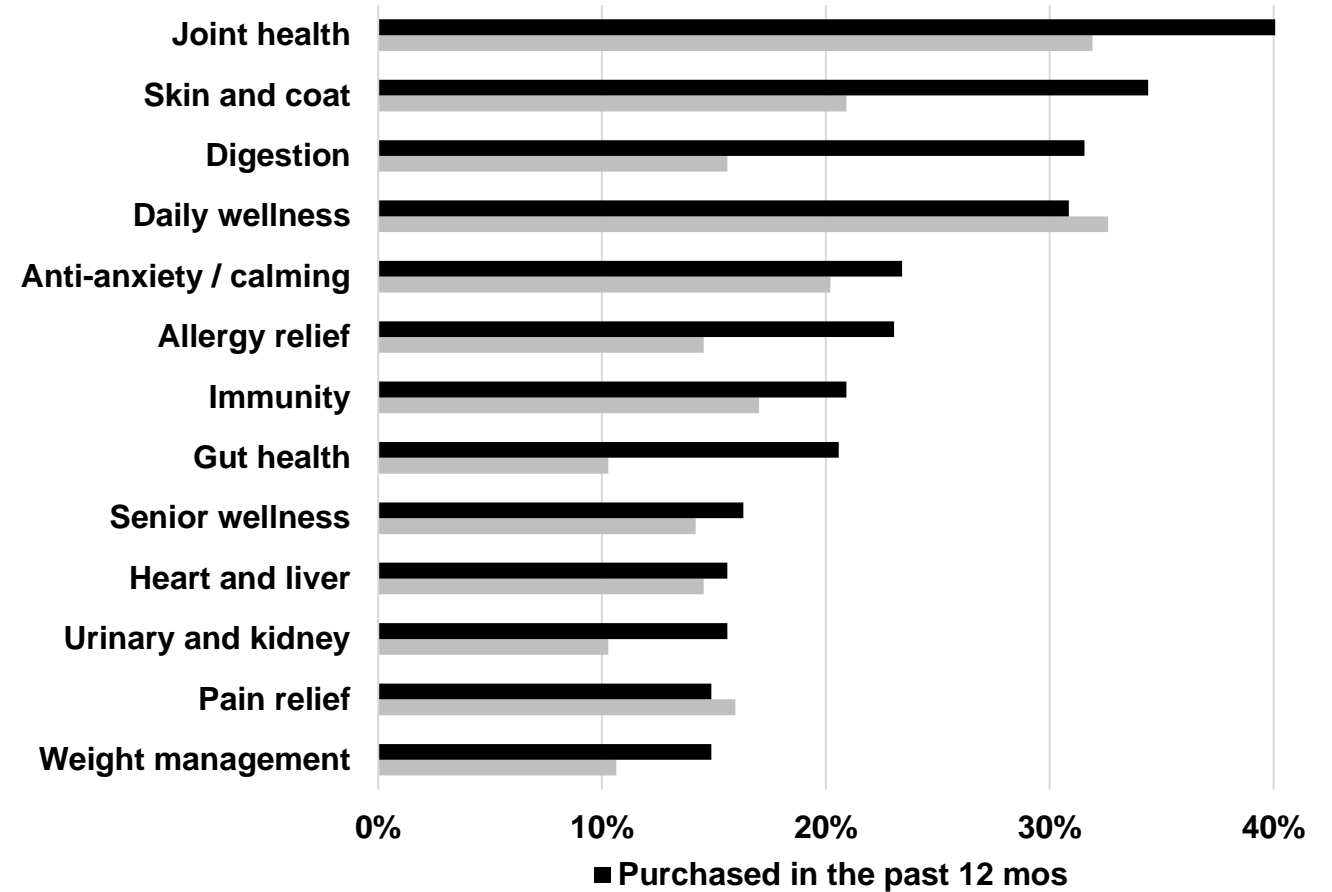
Source: 2023 Pet Parent Survey, marketplacebranding.com

# Most Sought After Benefits

## Benefits Driving Purchase vs. Consideration



Pet supplement audience (n=282)

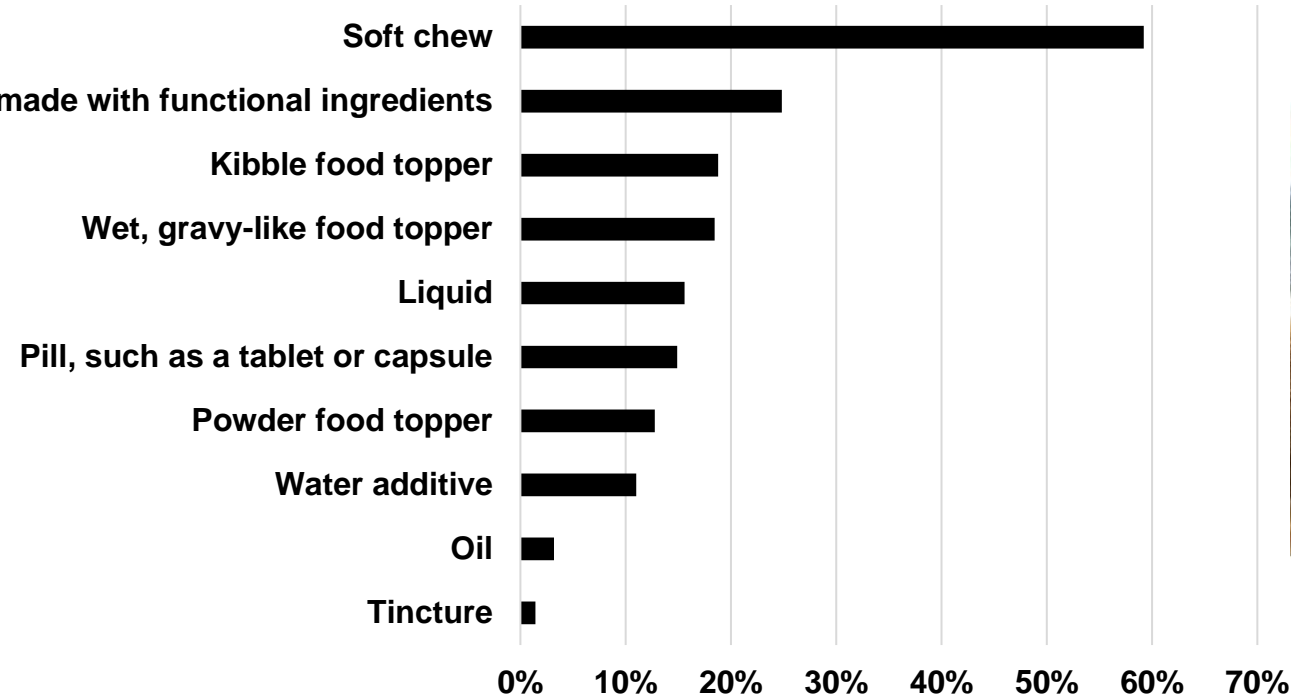


# Delivery Formats and Your Takeaway

## Soft Chews / Chewables Remain Preferred Format

**Danger, Danger**

A treat made with functional ingredients



Pet supplement audience (n=282); respondents were asked to select up to two.

# Now That The Marketing People are Excited Supplements v. Treats, the Law & the Risks

- In the US, DSHEA Does NOT Apply to Animals  
(Federal Register Notice, 4/22/96) - <https://www.govinfo.gov/content/pkg/FR-1996-04-22/pdf/96-9780.pdf>
  - Legally we have 2 choices for Animal Products: Food or Drugs
- Who Regulates These Products?
  - Food & Drug Administration, Center for Veterinary Medicine (FDA-CVM)
  - State Regulatory Agencies
    - ❖ Department of Agriculture
    - ❖ Other State Regulatory Agency: i.e. State Chemists Office

# What Does Federal Law Say?



- Federal Law: Food, Drug & Cosmetic Act & FDA Guidance Documents
  - The parts of the definition of a drug in Section 201(g)(1) in the Federal Food, Drug & Cosmetic Act [Title 21 of the United States Code, Section 321 (g)(1)] that indicate drugs are defined based on their intended use are 201(g)(1)(b) and 201(g)(1)(c) which state;
    - ❖ “(b) articles **intended** [emphasis added] for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and”
    - ❖ “(c) articles (other than food) **intended** [emphasis added] to affect the structure or any function of the body of man or other animals; ...”
  - Section 201(f) of the Federal Food, Drug and Cosmetic Act as, “(1) articles intended for food or drink for man or other animals... and (3) articles used for components of any such articles.” **Case law has defined articles of food ... as those articles which provide taste, aroma, or nutritional value, or technical effect (e.g. a preservative)**

# What do State Laws Say?

MO: <https://revisor.mo.gov/main/OneSection.aspx?section=266.160&bid=14380&hl=>

**266.160. Definitions.** — When used in sections [266.152 to 266.220](#) the following terms mean:

(2) **"Commercial feed"**, all materials or combinations of materials which are distributed or intended for distribution for use as feed or for mixing in feed, unless such materials are specifically exempted by the director. Unmixed whole seeds and physically altered entire unmixed seeds, when such whole or physically altered seeds are not chemically changed or are not adulterated within the meaning of subsection 1 of section [266.180](#), as well as wild bird seed, are exempt from the definition of commercial feed. The director by rule may exempt from this definition or from specific provisions of sections [266.152 to 266.220](#), commodities such as hay, straw, stover, silage, cobs, husks, hulls, and individual chemical compounds or substances when such commodities, compounds or substances are not intermixed with other materials and are not adulterated within the meaning of subsection 1 of section [266.180](#). Commercial feed shall not include feed that is manufactured, distributed and consumed by the manufacturer's own livestock;

(9) **"Drug"**, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man, and articles other than feed intended to affect the structure or any function of the animal body;



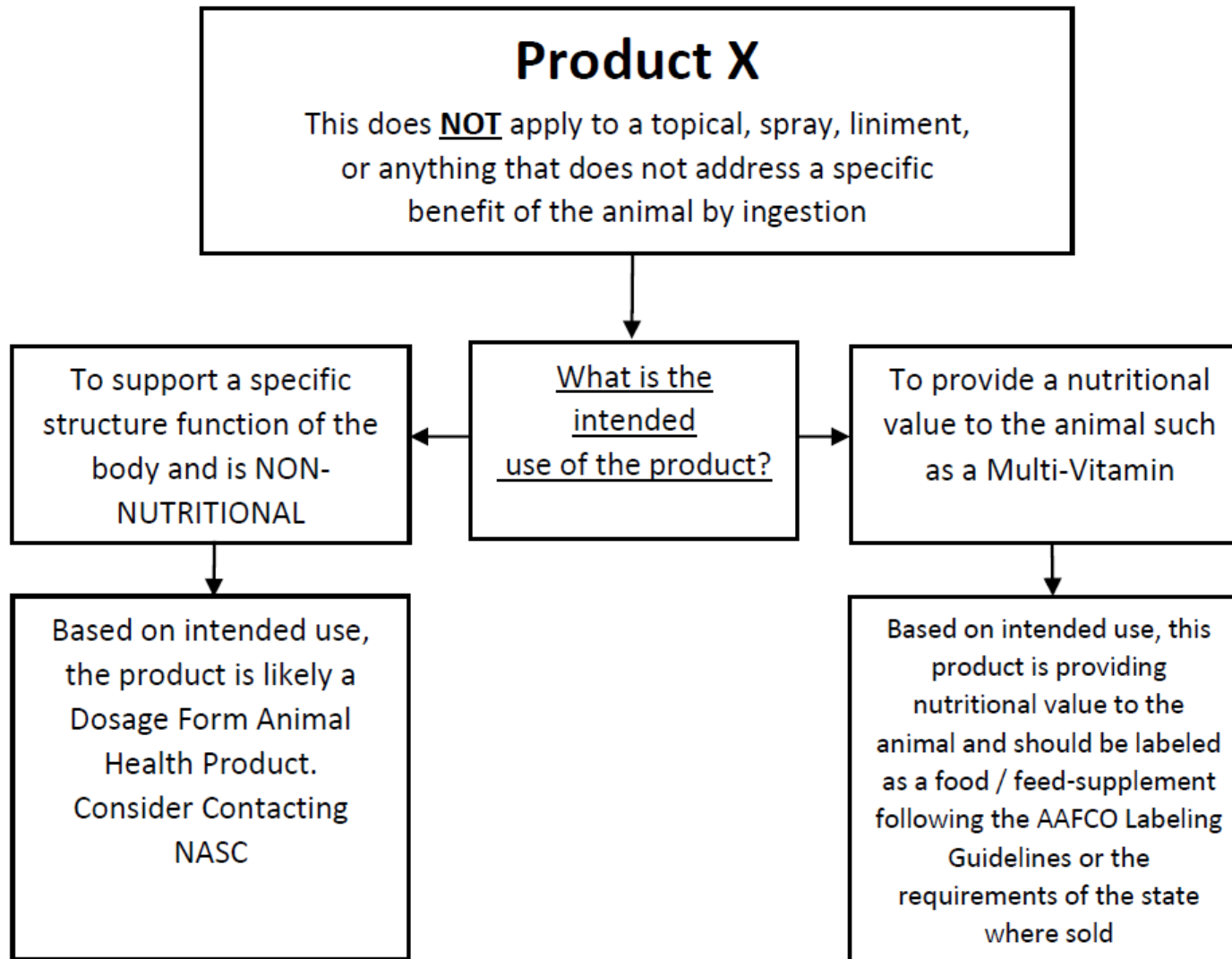
# What Does AAFCO Say?

<https://www.aaftco.org/resources/startups/definition-of-food-drugs/>

Under the Federal Food, Drug and Cosmetic Act (FFDCA) 201(f), a “food” is defined as articles used for food or drink for man or other animals...and articles used for components of any such articles. In part, **a drug is defined in the FFDCA 201(g)(1)(B) as a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and 201(g)(1)(C) an article (other than food) intended to affect the structure or function of the body of man or other animals.** The word “food” in the parenthetical “other than food” has been interpreted by the courts as an article that provides taste, aroma, and/or nutritive value. **Claims on animal feed labels are limited to those that can be attributed to the taste, aroma, or nutritive value of the food. Claims that indicate that a product can be used to diagnose, cure, mitigate, treat or prevent disease, or alter the structure or function of the body, in a manner or extent that exceeds its nutritive value, are not permitted on animal feed labels.**

For animals, the Food and Drug Administration Center for Veterinary Medicine (CVM) regulates two classes of products: food or drugs. Depending on the intended use, an animal food supplement product is considered either a food or drug. **There is no separate category for “supplements” for animals.** The term “dietary supplement” is defined in the Dietary Supplement Health and Education Act (DSHEA). On April 22, 1996, CVM published a notice in the Federal Register to explain that DSHEA does not apply to animal products. CVM has objected to the use of the terminology “dietary supplement” and their respective labeling on animal products. **Federal laws and regulations do not recognize a category of products for animals called dietary supplements. Depending on the stated intended use, a product is either a food or drug.**

# Primarily it is the Intended Use that Determines How a Product is Regulated



# What Type of Product is This?

- Is this Product a:

- Food / Feed, Treat
- Drug / Remedy,
- Don't know?



# And the Answer is ...



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For information see: <https://heartgard.com/>



# Health Supplements – Nutritional Supplements & Treats



- First Question is:

- What is the intended use as established by the claims?

- Followed closely by,

- ❖ What are the ingredients (do they support the intended use)?

- ❖ The delivery form can be a consideration along with any descriptive terms?

- Biscuit, Treat, Snack, Kibble, Cookie, Jerky, Gravy, Peanut Butter ... are food terms

- Other considerations:

- ❖ Adding to food or water = Food



# Summary: Under the Law, We have 2 and Only 2 Choices

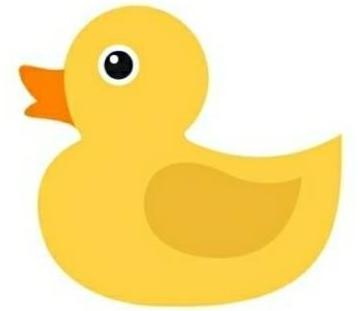
- **Food**
  - Intended Use is Nutritional
  - Ingredients are listed in AAFCO AND used for the approved Purpose
  - Descriptive Terms – one word can change the way a product is regulated
  - Treat – is a FOOD TERM
- **Drugs** (marketed under enforcement discretion, similar to human DS Products)
  - Intended Use is NOT Nutritional
  - Ingredients are NOT intended to for Nutritional Benefits
  - Size Matters – must be a Dosage Form Product:
    - ❖ Tablet, Capsule, Pill, Powder, Chewable
    - ❖ How big is TOO BIG?



# Functional Treats: Are These Possible?

- How are Treats Regulated?
- No Precedent to Leverage –
  - Are there functional Power Bars, Sports Drinks ...
    - ❖ Answer: Yes, but not with exotic ingredients
- Why does Size Matter?
  - Contributes calories or other nutritional considerations

If it looks like a duck,  
swims like a duck,  
quacks like a duck,  
it's probably a duck!

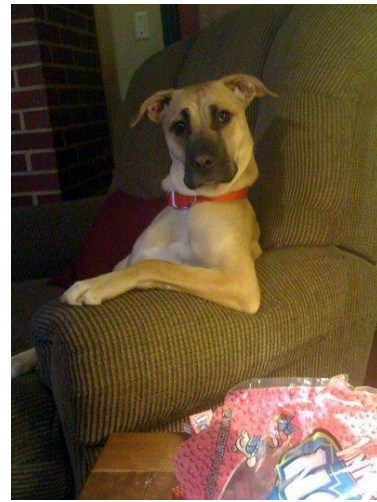


# What About Those Guys?

- Functional Treats –
  - I see these in the Marketplace; Why are they allowed?
- Lack of Enforcement Action doesn't mean it is OK ...
- What Functional Treats ARE OK?
  - Dental products that help remove Plaque and Tarter through mechanical and / or abrasive action within limits



# Deeper Dive for Dental Treats



## Acceptable claims

- Claims to cleanse or whiten teeth or freshen breath based on abrasive or mechanical action
- Claims for plaque or tartar reduction or prevention based only on abrasive or mechanical action
- Claims for control of bad breath odor based on masking flavor

# Deeper Dive for Dental Treats



## Not Acceptable

### (unless product subject of FDA Review and Acceptance)

- Preventing or treating dental disease or gum disease
- Ingredients not GRAS for intended purpose
  - Caprylic acid, sodium tripolyphosphate, tetrasodium pyrophosphate, aluminum calcium silicate, sodium fluoride
  - Exception: sodium hexametaphosphate (AAFCO defined as sequestrant)
- Claims based on any action other than abrasive or mechanical
  - Enzyme activity (e.g., glucose oxidase from *Aspergillus niger*)

# Other Land Mines Not to Step On for Food

- Our Ingredients are GRAS (Generally Recognized as Safe)
  - GRAS is species specific
  - GRAS for people does NOT = GRAS for Animals
- Hybrid Products
  - Example: Senior Dog Vitamin or a Treat with Unapproved Ingredients
  - Will likely be adulterated and misbranded
- Use of Approved Ingredients for Unapproved Purposes:
  - Section 582.10 AAFCO – OP
- Mix with Food or Water: consumer free will – you become a Feed Additive and regulated as Food



# So, What CAN You Do?



- Food:
  - Glucosamine and Chondroitin
  - Usually not objected to provided inclusion limits are followed and claims are limited:
    - ❖ Not to exceed 15 mg/kg/day for glucosamine hydrochloride and 12 mg/kg/day for chondroitin sulfate in rations or supplements for adult dogs
    - ❖ <https://otscweb.tamu.edu/Laws/PDF/Feed/FdInd-3-17.pdf>
  - Antioxidant Claims: usually not objected to but don't elaborate
  - Common Foods Index: new AAFCO program for “common & usual names”



# References

- Animal Food: [www.aafco.org](http://www.aafco.org)
- Events – Workshop in San Antonio, August 2024
- Resources:



- For Regulatory >
- For Industry >
- For Startups >
- For Laboratory & Proficiency >
- Testing
- Official Publication
- Guides and Manuals
- Find A Feed Control Official
- Online Courses
- Association Business Meeting Minutes

- Supplements:

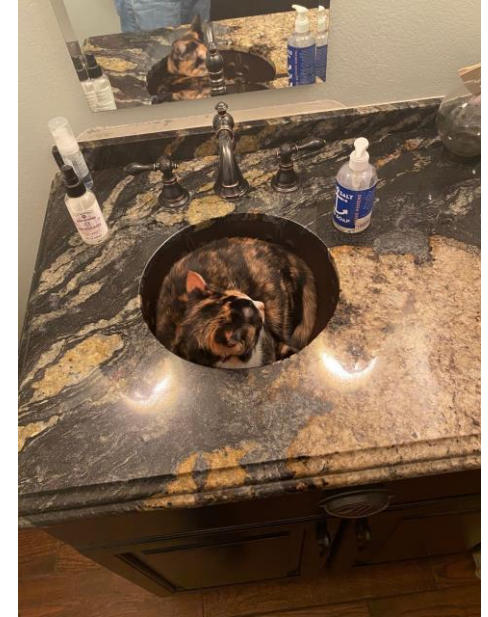
➤ [www.animalsupplements.org](http://www.animalsupplements.org)

- ❖ Health Supplements
- ❖ Nutritional Supplements



# Thank You

## Questions / Discussion / Contact Information



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