Regulatory & Quality Standards for Nutritional Supplements for Animals

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Quick Background
Outline

- Regulatory Language
- Laws, Regulations & Guidance
- DSHEA – What is it?
- Common Terms
- Regulations for Supplements for Animals
  - Food v. Drug
  - Food Regulatory Terms
  - Safety
  - Who Regulates?
Outline

- State Feed Regulation
  - Claims
  - Studies
  - Quality & Manufacturing
  - Other Regulations

● Substantiation for Claims
● Final Thoughts
● Questions
Regulatory Language

- FDA: Food & Drug Administration
- FTC: Federal Trade Commission
- CFSAN: Center for Food Safety & Applied Nutrition at FDA
- CVM: Center for Veterinary Medicine at FDA
- AAFCO: Association of American Feed Control Officials
- DSHEA: Dietary Supplement Health & Education Act of 1994
- FFDCA: Federal Food, Drug & Cosmetic Act
Regulatory Language

- **FDAAA:** Food & Drug Administration Amendments Act
- **FSMA:** Food Safety Modernization Act
- **CFR:** Code of Federal Regulations
- **cGMPs:** Current Good Manufacturing Practices
- **GRAS:** Generally Recognized As Safe
- **PDP:** Principal Display Panel
- **USDA:** United States Department of Agriculture
- **APHIS:** Animal & Plant Health Inspection Service
Laws, Regulations & Guidances

- **Laws** - enacted by Congress & signed by President
  - FFD&C Act
  - DSHEA
  - FSMA

- **Regulations/Rules** (implement laws)
  - Code of Federal Regulations
    - cGMPs

- **Laws can be self enacting** (no regulations)
  - Dietary Supplement & Nonprescription Drug Consumer Protection Act (serious AER reporting)

- **Guidance Documents** issued by FDA
  - Provides understanding of FDA’s current thinking
DSHEA – Dietary Supplement Health & Education Act of 1994

- Dietary Supplements for humans:
  - Intended for ingestion in tablet, powder, softgel or liquid form
  - Considered foods not drugs (no pre-approval)
  - Cannot be represented as a conventional food

- Examples of Regulatory Requirements:
  - Supplement Fact Boxes
  - Notices of structure/function claims to FDA
  - New Dietary Ingredient Notifications
  - Serious AER reporting
  - cGMPs
Common Terms to Describe Supplements

- Nutraceuticals
- Functional Foods
- Dietary Supplements
- Nutritional Supplements
  - Animal Side Reg Officials:
    - Do not officially recognize the terms nutraceuticals, functional foods or dietary supplements
    - April 22, 1996 Federal Register: CVM - DSHEA does not apply to products intended for use in animals
Regulations for Supplements for Animals – Food v. Drug

- No DSHEA – Either Food or Drug
- Food Definition (Food/Animal Feed):
  - Articles consumed primarily for their taste, aroma or nutritive value
- Drug Definition:
  - Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals... and articles (other than food) intended to affect the structure or any function of the body of man or other animals

- Presentation will focus on Food Category
  - Food/Animal Feed/Pet Food/Nutritional Supplements for animals
Regulations for Supplements for Animals – Food Regulatory Terms

- Foods – Safety is Key
- Regulatory Terms for Foods and Ingredients:
  - Approved Food Additives (FDA)
  - GRAS Petition/Affirmation/Self GRAS/Notices (forms of vitamin or minerals, nutrients, etc.)
  - Common or Usual Name (salt, sugar, water, oats)
  - Ingredient Definitions under/in AAFCO Official Publication – CVM No Objection Letter – Changing due to GRAS Notice acceptance by CVM
Regulations for Supplements for Animals - Safety

- Generally Recognized as Safe (GRAS)
  - Regulatory standard for ingredients found in food including food for animals
  - GRAS determinations do not have to be submitted prior to use to a federal or state regulatory official – Self GRAS
  - Ingredient is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use (species)

- GRAS Notice Process – Pilot on CVM side
  - Focus should be safety
Regulations for Supplements for Animals – Who Regulates?

- Regulated both at State and Federal Level
- Federal Level – FDA – Center for Veterinary Medicine
- State Level – State Chemist & Agriculture Offices
- Association of American Feed Control Officials (AAFCO)
  - Not a regulatory agency
  - 100 year old organization – help promote uniform regulation of animal feed
  - State and Federal Officials participate - create model bills for States to adopt
  - Forum for regulators to discuss and obtain consensus on animal feed regulations and enforcement issues
Regulations for Supplements for Animals – State Feed Regulation

- States – Food
  - Minimum Guaranteed Analysis instead of Supplement Facts - EXAMPLES
  - “Not recognized by AAFCO Dog/Cat Food Nutrient Profile” Language
  - Many States require products and/or companies register and report tonnage ($ fees)
  - Field Enforcement by States - retail and distribution level
Regulations for Supplements for Animals - Claims

- Regulatory agencies - Claims on Packaging (Educational Statements)
  - Generally do not object to maintenance or support of normal function – “source of ingredient and reference of support to a physiologic system or function (system support)
    - Support Joint Health
    - Maintain Joint Health
    - Omega-3 fatty acids for healthy coat OR help promote healthy skin and coat OR maintain healthy skin and coat
Regulations for Supplements for Animals - Studies

- Studies used to support supplements for animals
  - Product and ingredient specific
  - Do not assume studies on one particular product or ingredient specification can apply to all products
  - Generally not required to have all ingredients pre-approved by regulatory agency (Self GRAS concept)
  - No requirement for bioequivalence (generic)
  - Ask companies for scientific support and how it applies to their specific products and ingredients
Regulations for Supplements for Animals – Quality & Manufacturing

- Food Safety Modernization Act (FSMA) – Landmark law passed in 2010
- Several regulatory areas addressed in FSMA
- Focus here on manufacturing and quality
- New requirements to the food and feed industry
  - Requirements for GMPs, hazard analysis and risk management plans for feed, pet food and ingredients are new
  - Feed industry has only had medicated feed GMPs since 1971, but these have not applied to non-medicated feed
Regulations for Supplements for Animals – Quality & Manufacturing

- Current Good Manufacturing Practices (cGMPs), to include elements such as:
  - Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution
  - Preventive controls
  - Recordkeeping
Regulations for Supplements for Animals – Quality & Manufacturing

- Preventative Controls section will include:
  - Process Controls
  - Supplier controls
  - Sanitation controls
  - Submission of food safety plans written and include:
    - Hazard analysis
    - Preventive controls for hazards that are reasonably likely to occur
    - Recall plan for animal food in which there is a hazard that is reasonably likely to occur
    - Monitoring
    - Corrective action
    - Verification
    - Supplier approval and verification program
Regulations for Supplements for Animals – Other Regulations

- USDA APHIS – Import Permits for Animal Based Ingredients
- FDA – Prohibited Cattle Material Rule that requires recordkeeping & prohibits the use of certain cattle-derived materials in animal food – 21 CFR 589
- FDA - Public Health Security and Bioterrorism Preparedness and Response Act of 2002
  - Prior Notice of Imports
  - Registration of Facilities with FDA
  - Administrative Detention
  - Recordkeeping Rules – 1 up/1down
Substantiation of Claims

- Truthful and not misleading
- Evaluates “take away message”, net impression & consumer perspective
- Adequate substantiation for all objective product claims
Substantiation of Claims

- Competent & Reliable Scientific Evidence – FTC Requirement
  - Tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
Nutritional Supplements for animals are regulated by State & Federal regulatory officials – Food Category

Safety is Key

Companies must have certain processes in place to carefully evaluate product label, promotion and claims to:

- carefully evaluate safety
- ensure proper substantiation for claims
- work in a quality atmosphere and follows GMPs
- avoid express disease claims and closely evaluate all claims in its context and media
Final Thoughts

- Vets & Animal Health Care professionals
  - Challenge companies for science (peer reviewed and published studies)
  - Where is the Company physically located and where do they make their products (transparency)?
  - Proven track records – how long have they been in business?
  - Does the Company follow documented manufacturing practices and quality control
Questions??