

Behavioral Nutraceuticals and Diets

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KEYWORDS

- Behavior • Supplement • Nutrition • Treatment • Nutraceutical • Diet • Anxiety
- Cognitive dysfunction syndrome

KEY POINTS

- Nutraceuticals are regulated as food products, not drugs, despite their ability to modify an animal's health beyond meeting nutritional needs.
- Before prescribing a nutraceutical or therapeutic diet, veterinarians should review the literature supporting the use of the product and gather information on the functional ingredients, their mechanisms of action, efficacy, and safety.
- As with psychopharmacologic agents, behavioral nutraceuticals and therapeutic diets should only be prescribed in conjunction with behavior modification and environmental management plans.
- Some nutraceuticals and diets can be prescribed in combination with psychopharmacologic agents, but attention must be paid to the product's functional ingredients and mechanism of action so that adverse interactions are avoided.

INTRODUCTION

Terminology and Regulation of Nutraceuticals and Therapeutic Diets

The term “nutraceutical” has no legal or regulatory meaning. It was coined in 1989 by a physician who combined the words “nutrition” and “pharmaceutical” for the purpose of labeling the products that seem to fall between the categories of food and drug.¹ The Dietary Supplement Health and Education Act of 1994 defined the term “dietary supplement” as a product intended to supplement the diet that contains 1 or more of the following dietary ingredients: a vitamin, mineral, herb or other botanic, amino acid, dietary substance used by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combination of these ingredients [21 USC 321(ff)(1)].² However, in 1996 the Center for Veterinary Medicine, a subset of the US Food and Drug Administration (FDA), declared this term to be inapplicable to animal products because the Dietary Supplement Health and Education

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Act was only intended to apply to humans. Furthermore, the Center for Veterinary Medicine objects to the use of the term dietary supplement when describing animal products because it may falsely imply applicability of the Dietary Supplement Health and Education Act and its regulations of human supplements.³ The North American Veterinary Nutraceutical Council, which was formed in 1996 and has since disbanded, defined nutraceutical as a nondrug substance that is produced in a purified or extracted form and administered orally to provide agents required for normal body structure and function with the intent of improving the health and well-being of animals.⁴ Despite this fitting definition, the term nutraceutical still has no legal meaning for the purposes of regulation.

So what do we call these products and how are they categorized? Veterinarians still generally refer to these products as nutraceuticals because this seems to be the best descriptive term. However, for a legal classification, we must look back to the Federal Food Drug and Cosmetic Act of 1938. It vaguely defines “food” as articles used for food or drink for man or other animal [21 USC 321(f)].² A legal ruling in 1983 established a more detailed definition for food as an item consumed primarily for taste, aroma, or nutritive value.³ Legally, nutraceuticals are regarded as food and, therefore, are not required to provide premarket safety and efficacy data to obtain clearance from the FDA as do pharmaceutical products. However, nutraceutical ingredients must have already been determined to be generally regarded as safe as defined by the FDA, be an FDA-approved food additive, or fit the definition of ingredient as listed in the Association of American Feed Control Officials book.¹ If the ingredients do not follow these rules, the product will be considered “adulterated” and, as such, is subject to FDA enforcement actions.³ If a nutraceutical manufacturer makes claims that their product can treat or prevent a disease, then it fits the definition of a drug rather than a food. The term “drug” is defined by the Federal Food Drug and Cosmetic Act as any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal [21 USC 321(g)(1)].²

Legal oversight of nutraceutical products is generally lax. Enforcement of laws against nutraceuticals making drug claims are considered to be of low regulatory priority, and violations are not commonly acted on by the FDA.³ In addition to the FDA, there are also state-level agencies, such as the state department of agriculture, that will monitor nutraceuticals. Many states follow regulations published by AAFCO and require that manufacturers register or obtain a license with their state before distributing their product.³ Responsibility lies with the manufacturer to ensure the product is labeled appropriately. The state can review the label and, if it is found to be noncompliant, the manufacturer may be denied registration or licensure. However, the thoroughness of the review can vary. Some violations may be overlooked to maintain uniform enforcement or because they are of low priority.³

Nutraceutical manufacturers may opt to join trade organizations such as the National Animal Supplement Council. The National Animal Supplement Council requires certain labeling and manufacturing standards of its members and has an adverse event reporting system. Manufacturers who comply with regulations are allowed to use the National Animal Supplement Council seal on their product label. Nutraceutical manufacturers may also enlist the services of independent quality assurance companies such as ConsumerLab, NSF International, or the United States Pharmacopeia. These companies offer services such as facility inspections and laboratory testing to ensure ingredient strength matches label claims and to check for contamination. Qualifying products can use the company’s seal on their labels.

Another area of terminology that can confuse veterinarians is that of therapeutic diets. These are the foods produced by manufacturers to provide specialized support to

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