Dietary Supplements – What You Should Know

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What is a dietary supplement?

A dietary supplement is administered, in addition to a horse's ration, to generally improve or maintain health. Common supplements include vitamins, minerals, botanical and herbal preparations, enzymes, amino acids, and live microbials (also known as probiotics). Dietary supplements are not intended to be food or drugs and come in many forms, including tablets, powders, paste, and liquids. They are commonly sold in tack shops and/or online and do not require a veterinary prescription.

What is a drug?

Under the Federal Food, Drug, and Cosmetic Act, the term "drug" means a product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles other than food intended to affect the structure or any function of the body. The Food and Drug Administration (FDA) strictly monitors drug products, including their ingredients, manufacturing processes, and marketing, including package labeling and other product claims.

What makes a product an Approved New Animal Drug?

Veterinary drugs approved for sale in the United States are subject to a stringent approval process examining their safety, stability, potency, and efficacy. If approved by the FDA, they are considered safe and effective when administered according to label directions.

Why are dietary supplements not regulated?

The FDA does not have the legal authority to approve supplements. This means that supplements are not evaluated by the FDA for safety, purity, stability, potency, or efficacy prior to their sale. It is, therefore, the responsibility of the manufacturer to ensure the product's safety and to market the supplement in accordance with applicable law.

What's on a label?

FDA-approved drug products are permitted to include health claims that characterize a relationship between a drug product and a disease or a health-related condition. In other words, a health claim describes the effects a substance has on reducing the risk of, preventing, mitigating, treating, or curing a disease or illness. A health claim requires FDA evaluation and authorization prior to its use by a manufacturer. The label on an approved drug is also permitted to have a structure/function claim involving a direct or indirect effect on the body.

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Examples of health and structure/function claims are:

- Decreases or prevents Exercised-Induced Pulmonary Hemorrhaging (EIPH).
- Prevents or treats gastric ulcers.
- Manages pain caused by osteoarthritis.
- Controls inflammatory airway disease.
- Increases cardiac output.
- Increases red blood cell production.

In contrast, dietary supplements have a "Supplement Facts" label and are only permitted to include claims that suggest benefits to general well-being.

Examples of permitted statements on Dietary Supplements are:

- Sustains lung health.
- Maintains gastrointestinal health.
- Supports heart health.
- Supports bone strength.
- Promotes healthy metabolism.
- Replenishes electrolytes lost through exercise and sweating.

If the product and its marketing have not been approved by the FDA, but the product's labeling or marketing includes a health or structure/function claim, the product is a drug, not a dietary supplement. Without approval by the FDA, it is an unapproved new animal drug and is designated as a Banned Substance (S0) under HISA's rules.

Remember:

- "Natural" does not mean safe, nor does it mean that a product is free of Prohibited Substances.
- Seals of quality assurance by a manufacturer do not guarantee that a supplement is safe or effective.
- Supplements can interact with some medications with adverse health outcomes; be vigilant and discuss administration with your veterinarian.
- Dietary supplements are not, and do not replace, prescription medication.
- Although not regulated by the FDA, the FDA can take action to remove supplements from the market if they are adulterated (unsafe) or misbranded (misleading).

*Please be advised that the responsibilities and requirements set forth above are contained in the Anti-Doping and Medication Control (ADMC) Program regulations submitted by the Horseracing Integrity and Safety Authority to the Federal Trade Commission (FTC). These regulations were approved by the FTC on March 27, 2023. The information enclosed herein is not exhaustive, and more information can be found by consulting the approved regulations, which were posted to the Federal Register on January 26, 2023.

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