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The Texas A&M University System
Originally Issued as Feed Admn. Memo Feb. 2, 1999
Revised Nov. 14, 2006 as Feed Industry Memorandum

FEED INDUSTRY MEMORANDUM NO. 3-16

Regulation of DSHEA Authorized Dietary Supplements for Humans when used as or in Animal Feeds

OBJECTIVE

To detail the conditions under which these products which are neither approved drugs nor approved feed ingredients may be distributed.

BACKGROUND

In October 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA) creating a new regulatory scheme for "dietary supplements." These are defined "as a product, other than tobacco, which are intended to supplement the diet that contains at least one or more of the following ingredients: a vitamin, a mineral, herb or other botanical, an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake, or a concentrated metabolite, constituent, extract or combination of any of the previously mentioned ingredients." The main effects of DSHEA are to remove dietary supplement ingredients from the requirements of having to provide safety and efficacy data prior to approval by the FDA, to allow substitution of safety data based on historical uses for controlled studies, and to allow certain limited claims to be made without the dietary supplement being classified a drug.

DSHEA does not explicitly state whether it includes or excludes products intended for use in animals. However, the FDA as published in the *Federal Register* on 4-22-96 has determined that DSHEA does not apply to animal products. The FDA cites the following reason for this ruling: (a) language in DSHEA implies that Congress only had humans and not animals in mind when passing the legislation; (b) public health concerns via food safety as residues in animal diets and foods are for the most part unknown in regards to "dietary supplements"; (c) while the safety of these products in humans is mostly established by their having a long history of safe use, the same information is generally not available for animals; (d) animal species differ in their reactions to different products; and (e) courts have confirmed that it was congressional intent to limit DSHEA to humans (U.S. versus Solid Gold Holistic Animal Equine Nutrition Center, et al.).

Nevertheless, many states are allowing incorporation of these products into feeds or their sale as feeds; thus, it is necessary to define the conditions under which products generally known by the marketing terms nutraceuticals, functional foods/feeds, designer foods/feeds, etc., may be distributed under the Texas Feed Law.

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In formulating this policy, the Service relies on the following: §141.002(d) of the Law and §61.2 of the Rules.

POLICY

1. All products containing any materials approved under DHSEA for human use, but not approved by the FDA as appropriate for inclusion in animal feed are "adulterated" and distribution must be restricted.
2. In addition to meeting all other requirements of the Law and Rules, firms wishing to distribute such products in Texas shall:
 - a) provide the Service with safety data acceptable to the Service and with an analytical method capable of determining the material at a level 50% less than guarantee;
 - b) if efficacy claims are made, provide the Service with data acceptable to the Service demonstrating efficacy;
 - c) distribute product only to licensed veterinarians;
 - d) execute a standard agreement with licensed veterinarians that such products will be distributed in the climate of a valid, client-patient/veterinarian relationship, report any adverse reactions to the Service – adverse reactions defined exactly as does the FDA – and will not floor-stock the item for public sale;
 - e) provide at the Service's request a copy of the veterinarian's signed agreement.

REGULATORY ACTIONS

1. Products found at feed stores, tack shops and shows and publicly displayed as retail items in the veterinarians' offices shall be stop-saled.
2. Should there be doubts, notify the Office and we will ask for a copy of the firm's agreement with the veterinarian.



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