The Agriculture Program
THE TEXAS A&M UNIVERSITY SYSTEM • EXPERIMENT STATION
Feed and Fertilizer Control Service • Agricultural Analytical Services

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FEED INDUSTRY MEMORANDUM NO. 5-19

SUBMISSION OF ADDITIONAL INFORMATION PRIOR TO DISTRIBUTION OF "NUTRACEUTICALS" OR PRODUCTS CONTAINING NUTRACEUTICALS

OBJECTIVE:

To ensure products which are not recognized by the FDA as safe and effective for animal use or do not possess GRAS animal status are neither misbranded nor adulterated under 4 TAC 141.

BACKGROUND:

Many states are allowing incorporation of dietary supplements.[1] The Service's historic position has been that any claims made with respect to the performance of a particular feed or fertilizer must be valid and the purpose of the inclusion of drugs in feeds, pesticides in fertilizers or other special purpose additives in either feed or fertilizer must be stated in the registration and on the labeling of products. The safety and/or efficacy of the products must have been established when used in accordance with directions which must also appear on the labeling. The levels of additive required to perform the purpose claimed must be present at all times and appropriate label warnings concerning misuse are required for the protection of users.

The Control Service is fortunate to be a part of a land grant university, thus having immediate access to a variety of knowledge through contacts with specialists in the fields of veterinary medicine, animal science and soil and crop sciences and others. When it becomes necessary to render a decision with respect to the acceptability of registration of a product which through its labeling claims to be effective for certain specific purposes, the Service has at its disposal technical representatives appointed by the Director to assist in determining whether the scientific basis for such claims is sound.

When such advice is necessary, the committee is supplied with the data which the applicant for registration is required to furnish. The data are reviewed and evaluated and suggestions concerning the acceptance, rejection or modification of the request are submitted for the consideration of the staff of the Control Service.

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[1] Those products other than tobacco which are intended to supplement the diet and which contain at least one or more of the following ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid; a dietary substance used 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.

Such technical advisory committees are appointed by the Director of the Texas Agricultural Experiment Station.

In developing this policy the Service has relied on §141.002, §141.147, §141.148(a)(6) and (a)(9) of the Feed Law; §61.2(b)(1) and §61.11 of the Commercial Feed Rules and §63.2(o)(2), §63.2(o)(4) and §63.7 of the Pet Food Rules.

POLICY:

All animal feed products containing any materials approved under DHSEA for human use, but not approved by the FDA as appropriate for inclusion in animal feed or not GRAS for animal feed are "adulterated" and specific permission to distribute must be obtained prior to distribution regardless of whether a firm possesses a license.

Such adulterated feed can be distributed only through licensed veterinarians under the following conditions:

1. A valid patient-client-doctor relationship must exist.

2. Firms must ***first*** provide the FFCS acceptable safety data and provide an analytical method capable of determining the material at a level of 50% less than the guarantee. The data shall be submitted to the Service in one indexed volume accompanied by a check in the amount of $2,000.00. The fee is **not refundable**.

3. If the firm makes efficacy claims, it must provide FFCS with acceptable data demonstrating such efficacy.

4. The firm must execute a standard agreement with a licensed veterinarian stating that:

   a. such nutraceuticals will be distributed only in the climate of a valid client-patient-veterinarian relationship;

   b. any adverse reactions will be reported to the FFCS by the veterinarian;

   c. such nutraceuticals will not be floor-stocked for public sale.

5. The firms may upon request be required to provide FFCS with a copy of the required agreement(s) with the veterinarian(s).

For the Office,

Dr. A. Konrad Dugster
Associate Vice Chancellor of Agriculture

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