CORRESPONDENCE/MEMORANDUM STATE OF WISCONSIN

Department of Agriculture, Trade and Consumer Protection **Bureau of Agrichemical Management**

DATE: October 03, 2018

TO: Management Team

FROM: Heather Bartley, Commercial Feed Program Manager

SUBJECT: Labeling of Dosage Form Animal Health Supplements for Non-human Food Producing Animals

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Under Wisconsin commercial feed regulations, Wisconsin Statute §94.72 and Wisconsin Administrative Code ch. ATCP 42, commercial feed includes all materials making up or wholly comprising a product intended for consumption by animals or birds. By popular demand, the humanization of certain species (for example: horses, dogs and cats) has resulted in the emergence of animal health supplements, referred to herein as dosage form supplements. These supplements are similar to dietary supplements for humans.

Under Federal Law, the Dietary Supplement and Health Education Act (DSHEA) of 1994, has affected the way the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) regulates "food for humans." Among other things, it restricts substances from being food additives or drugs if the product meets the definition of a dietary supplement.

However, FDA's assessment of DSHEA is that it was not intended to, and does not, apply to animal feed, including pet food[1]. Thus, products marketed as dietary supplements or "feed supplements" for animals still fall under Title 21, the Federal Food, Drug, & Cosmetics Act (FFDCA). These items are considered "foods" or "drugs" depending on the intended use, or in some instances the articles may be, simultaneously, a food and a drug.

The regulatory status of an article is determined by CVM on a case-by-case basis, using criteria provided in the FDA/CVM Program Policy and Procedures Manual Guide 1240.3605. The three specific articles that have a legal status as both a food and a drug simultaneously are in the table excerpt below:

Article	Intended Use	Legal Status	Regulate As
Animal Feed or Food	Structure or Function – (g)(1)(C), excluding production claims[2]	Drug – 201(g) Food – 201(f)	Food
Nutritional Ingredient	Prevention of nutritional deficiencies – (g)(1)(b) excluding diagnosis, cure, mitigation, treatment	Drug – 201(g) Food – 201(f)(1) & (3) – 201(s) substance	Food
Nutritional Ingredient	Structure or Function – (g)(1)(C), excluding production claims[2]	Drug – 201(g)[3] Food – 201(f)(1) & (3) – 201(s) substance	Food

[1] Specified assessment was published in the Federal Register on April 22, 1996 (61 FR 17706).

[2] Claims for improving animal production, such as increased milk production, increased leanness, and improved growth and efficiency of gain. Such claims are not permitted in animal feed or nutritional ingredients.

The Department has jurisdiction over commercial feed for animals. The Department does not have jurisdiction over animal drugs, or over articles that are simultaneously a food and a drug. Certain dosage form supplements on the market for non-human food chain animals (i.e. horses, dogs, cats) fall into one of the categories identified in the table above, making them a food and a drug simultaneously. Such articles are not regularly reviewed by the FDA, and are placed in a low enforcement priority.

To align with the FDA's enforcement and review strategy, the Commercial Feed Program will place a low enforcement priority on dosage form supplements only if both of the following conditions are met:

1. The intended species is dogs, cats, horses, or another animal ***NOT*** used to produce food for humans, and
2. The label format is that of a drug, according to 21 CFR §510. For example, the product label will include identification of one or more active ingredients and one or more inactive ingredients, instead of a guaranteed analysis accompanied by an ingredient statement.

Basic guidance and direction on a drug label format, specific to this policy, will be developed by the Commercial Feed Program, and made readily available to the regulated community. Also, guidance and direction specific to this policy will be developed by the Commercial Feed Program, and made readily available to staff within the Investigation and Compliance Section.

In the event the FDA revises their current enforcement and review strategies of any articles that are simultaneously a food and a drug, the Commercial Feed Program will realign this policy to identify and report such dosage form supplements to FDA for governance as new animal drugs.

Although DATCP does not have authority involving the enforcement of labeling requirements for animal feed products [e.g., drug(s)] that do not include a single nutritive item, value or guarantee; DATCP, in partnership with the FDA, has referred the manufacturers of these product type(s) and/or individual products to the FDA's Center of Veterinary Medicine for further compliance related actions.

In order to abide by the FDA's enforcement strategy regarding dosage form animal health supplements, DATCP will place a low priority on the review and referral of these products. This will allow dosage form animal health product manufacturers/labelers/distributors to continue to distribute their products within the state. However, in the event that an animal illness/death arises from the consumption of a dosage-form supplement, the Department will conduct a formal investigation and may refer its findings to the FDA/CVM. Additionally, in the event that manufacturers/labelers/distributors make egregious drug claims, the Department will continue to pursue any formal enforcement action(s).

Lastly, manufacturers/labelers/distributors of dosage form supplements for non-human food producing animals continue to be required to hold an active Wisconsin commercial feed license, report annual tonnage, remit annual inspection fees, and with the exception of labeling requirements, license holders will continue to be inspected for compliance with Wisconsin commercial feed regulations.

Determination 1: Wisconsin commercial feed labeling requirements [reference Wis. Admin. Code §ATCP 42.04(2)] are unrelated to dosage form animal health supplements, as defined by FDA/CVM as "simultaneous food and drug products" in "tablet, capsule, powder, or liquid form…considered drugs because they are intended to prevent/treat disease or affect the structure or function of the animal other than providing nutrition, taste or aroma."

The two label components unrelated to the purpose of dosage form animal health supplements for non-human food producing animals are the guaranteed analysis and ingredient statement.

A guaranteed analysis on a dosage form supplement label will not be required, as the purpose of these supplements are non-nutritive, thus making nutrient guarantees irrelevant.

In lieu of an ingredient listing, dosage form supplement labels must contain a listing of both the active and inactive ingredients, so as to identify to the consumer which ingredient will provide the desired body-structure and/or function support. Furthermore, identification of active and inactive ingredients in and of itself depletes the need for an ingredient statement, as an ingredient statement would be duplicative if complete and in descending order of predominance by weight [reference Wis. Admin. Code §§ATCP 42.16(1), 42.32(1)(Note) & 21 CFR §501.4(a)], *or* an ingredient statement would be noncompliant if continuity of the active versus inactive ingredient listings were maintained [reference Wis. Admin. Code §§ATCP 42.16(1) & 42.32(1)].

Determination 2: The FDA/CVM Program Policy and Procedures Manual Guide 1240.3605 allows scientifically-supported body-structure/function claims related to some ingredients used to manufacture dosage form animal health supplements for non-human food producing animals. Such claims typically are not written into the regulatory-recognized definition and approved use(s) of said ingredients.

Under Wisconsin commercial feed labeling requirements, such uses are prohibited by Wis. Admin. Code §ATCP 42.50(3)(a), "…no person may manufacture or distribute any commercial feed containing a special purpose additive or non-nutritive additive if …The additive is not safe, or is not effective, for its intended use when used according to label directions, or the additive is used in the commercial feed for a purpose other than that for which it was intended, or in violation of its label."

Review of such scientific evidence has been the responsibility of FDA, and will continue to be the responsibility of FDA under the FFDCA. If the Department finds a suspect product, the Department will refer the article and any accompanying label and/or labeling to the FDA for review.

Determination 3: Additional guidance is available through the FDA website, by researching/reviewing 21 CFR §510. In the event FDA/CVM publishes new or different guidance, the Feed Program will re-assess this policy.

Other Considerations:

1. Low enforcement priority exercised under this policy will not apply to animal supplements that are labeled for use in human food production animals.

2. Issuance of Certificates of Free Sale for dosage form animal health supplements, intended for non-human food producing animals, will be referred to the FDA/CVM, as such articles are animal drugs.

3. Additional information regarding dosage form supplements is available through the National Animal Supplement Council (NASC). However, access to this information would require the company using it to obtain membership into the NASC. Membership fees are assessed based on the level of membership attained.