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FEED SUPPLEMENTS FOR HORSES: BUYER BEWARE

The following article was adapted from a speech presented by Sharon A. Benz, Ph.D., PAS to the Annual Meeting of the American Horse Council, June 3, 1996, Washington, DC. The article provides information on feed supplements for horses which may be helpful for owners in making their purchasing decisions. Veterinarians and equine nutritionists may wish to duplicate this article and provide copies to their interested clients. As always, material which appears in the FDA Veterinarian is free of copyright and may be reproduced without permission.

FDA's Center for Veterinary Medicine is responsible for the regulation of animal drugs, medicated feeds, animal food additives, and devices for use in animals. Feed ingredients, food additives, and drugs used in horse feeds and supplements are subject to the exact same laws as feed ingredients, food additives, and drugs for other domestic animal species. These products are also regulated in the exact same manner.

Everyone who owns a horse wants it to look and perform at its best, and part of this is good nutrition. Therefore, owners are often searching for new feed supplements that will improve the horse's health or provide a competitive edge in the show ring or on the race track. Unfortunately, the subjective nature of most of the evaluations of equine performance lends itself to the promotion and sale of many dubious products. These products may not pose an imminent health threat to a horse, that is, if a horse eats them it will not be acutely harmed. However, the effects of their long-term or high-level use may not be known or their usefulness may not be supported by valid scientific research.

Legal Background

While most of us call the grains, hays, etc. that horses consume "feed," the Federal Food, Drug, and Cosmetic Act (the Act), defines it as food. That is, food is an article used for food or drink for man or other animals. In a precedent-setting judicial decision, "food" was described as an article that provides taste, aroma, or nutritive value. Foods are considered generally recognized as safe or GRAS as sources of taste, nutrition, or aroma.

A food additive as defined by the Act is a substance which directly or indirectly becomes a component or otherwise affects the characteristics of a food. A substance is not a food additive if it is generally recognized as safe (GRAS) for its intended purpose by scientists qualified by training and experience to make such a determination. Some examples of food additives are anticaking agents, pelleting aids, and preservatives. Under the Act, a food additive is unsafe unless a regulation is promulgated providing for its safe use.

The definition of a drug is pretty straightforward. A drug is any substance, food or non-food, that is used to treat, cure, mitigate, or prevent a disease. A drug is also any non-food substance that is intended to affect the

structure or function of the animal. Drugs must be shown to be safe and effective for their intended use. Any product administered by injection is also considered a drug.

Part of what distinguishes a food from a drug or a food additive is the intended use. For example, when vitamin E is used as a source of an essential dietary nutrient, it is considered a food. If it is used to treat or prevent azoturia or tying up syndrome, it is a drug. The legal distinction between a food and a drug is critical in terms of FDA's regulatory authority. A new drug or new animal drug must be subject to an approval process prior to marketing. Adequate data from controlled scientific studies to demonstrate the safety and efficacy of the drug for its intended use are required before a drug may be approved. Unapproved drugs on the market are deemed adulterated drugs and may be subject to regulatory action. In contrast, the law does not require a food to be subject to a premarket approval process unless it is considered to be a food additive.

Going back to the vitamin E example, if the label for a vitamin E supplement bears claims that consumption of the product will treat, prevent, or otherwise affect azoturia or tying up syndrome, such claims establish the intent to offer the vitamin E supplement as a drug. Furthermore, since vitamin E is not approved for this use, it is considered an unsafe new animal drug under the Act. This vitamin E supplement would be subject to regulation by FDA as a drug as well as a food. A company must remove the drug claims to restore its regulatory status as a food.

Lastly, there are various products being called "nutraceuticals." There are no laws or regulations that define what a nutraceutical is. The term was coined to describe the increasing number of products offered for the prevention or treatment of disease but marketed under the guise of food supplements. These may include products that contain levels of essential nutrients beyond what is recognized for normal nutrition or contain nutrients that are not recognized as essential for the intended species, such as omega-3 fatty acids. Presently, these substances are considered new animal drugs if the labeling bears claims to treat or prevent disease. The Dietary Supplement Health and Education Act that was recently passed by Congress limits FDA's authority regarding these types of substances for humans. However, CVM's assessment of the new law is that it was not intended and does not apply to animal feeds. This assessment was published in the Federal Register on April 22, 1996.

Specific Examples

The following are specific examples of unapproved products and a discussion of why horse owners should think twice before buying them. The first group of supplements is products which fill no recognized nutritional need in the horse's diet. There are no acceptable research studies in peer-reviewed journals, nor has the Agency seen information to support the safety and usefulness of these products. Most of these products have only anecdotal information and some case studies attributed to them.

An example of this type of product is Gamma Oryzanol, which appears to be a relatively new product in the horse industry that is being publicized as a growth promotant and as a safe natural alternative to anabolic steroids. Gamma Oryzanol is an extract of rice bran and has not been proven safe or effective for use as a growth promotant in horses. There is one growth promotant approved for use in horses. That approval is for chlortetracycline for use as a growth promotant in horses under one year of age.

Octacosanol is a substance that is being promoted to improve endurance and speed reaction time, to strengthen muscles and to reduce oxygen debt. This substance is found naturally in small amounts as a component of plant

waxes and some vegetable oils, notably wheat germ oil. It has not been shown to be safe and effective for any use in horse feeds.

Superoxide dismutase (SOD) or Dismutase is an enzyme that has a number of important oxidative functions in cells including red and white blood cells and muscle cells. It is often sold as a feed supplement for treatment of musclo-skeletal inflammation and stress, and for disease prevention. Since enzymes are proteins and proteins are digested in the gut, SOD would also be digested in the same way as other proteins in the diet are digested to amino acids or peptides for absorption. Therefore, it is unlikely that any intact enzyme would be absorbed and available to the cells in a horse's body. This product is basically a very expensive protein source.

Mucopolysaccharides are being promoted for use in feeds to increase synovial fluid viscosity in the joints and improve and strengthen the integrity of the joints. Mucopolysaccharides are components of connective tissue and joints. There are various forms of mucopolysaccharides on the market, such as glycosaminoglycans and chrondroitin sulfates. The products are most often derived from bovine trachea, animal cartilage, and Australian perna canaliculus mussel. When these products are promoted to treat non-infectious degenerative joint dysfunction of carpal joints in horses or to increase synovial fluid viscosity in the joints, they are considered unapproved new animal drugs because they have not been proven to be safe and effective for these purposes. When given orally, there is a question as to the extent of absorption of these compounds and how they reach the affected joint in sufficient amounts to have any effect.

Other products that are being promoted as digestive aids and sources of minerals are just normal components of soil such as humic acids and montmorilonite. Humic acids are the decomposition products of organic matter, particularly dead plants, and are found in the soil. Montmorilonite is a type of clay found in the soil which is permitted for use in the feed industry as an anticaking agent in feeds. These compounds are not approved and not shown to be safe as digestive aids and have not been proven to serve as a source of minerals to animals.

Diatomaceous earth, another substance taken from the soil, is being promoted as a natural dewormer. It is the silicon skeletons of ancient plankton that settled to the sea floor. It is an approved food additive as an anticaking agent or as an inert carrier not to exceed 2 percent of the diet. As a dewormer, it would be considered an unapproved new animal drug, and has not been shown to be either safe or effective for this purpose. In fact, there was a recent study that found diatomaceous earth was ineffective as a dewormer. This study, completed at the Virginia-Maryland Regional College of Veterinary Medicine, concluded that diatomaceous earth had no effect whatsoever on fecal egg counts or packed cell volume in sheep.

There is a product being promoted as vitamin B-15. It is also called Pangamic Acid and sometimes Dimethylglycine (DMG). Pangamic acid is a poorly defined chemical mixture allegedly isolated from apricot pits. These products may vary considerably in the composition. Some are mixtures of calcium gluconate and DMG and others contain diisopropylamine dichloroacetate, which is a drug. Pangamic acid is neither a vitamin nor a dietary requirement for any animal. Proponents claim that it decreases lactate production and plasma lactate levels after exercise and that it improves speed. Neither pangamic acid or DMG or diisopropylamine dichloroacetate has been proven safe or effective for any use in horse diets.

Another group of products includes nutrients that are being promoted for therapeutic effects. Tryptophan and magnesium are two nutrients--tryptophan is an amino acid and magnesium an essential mineral--that are being marketed for sedative and calming purposes. The amounts being used greatly exceed that needed for nutritional purposes. Tryptophan has been the subject of much scrutiny since several people who took tryptophan

supplements developed Eosinophilic Myalgia Syndrome, which is a painful and crippling nerve degeneration disorder. Tryptophan is generally recognized as safe (GRAS) to improve the quality of the protein source at nutritional levels. Tryptophan has not been shown to be safe and effective for use as a sedative. Moreover, giving tryptophan in large doses for sedative purposes can cause severe amino acid imbalances and deficiencies in other amino acids, and can also be toxic. Similarly, large doses of magnesium can interfere with the utilization of other minerals and result in mineral imbalances.

Phenylalanine is another amino acid that is often promoted for therapeutic purposes as a painkiller. Phenylalanine is also GRAS when added in small quantities to diets to improve protein quality. It is not approved and has not been shown to be safe and effective as a painkiller. Like tryptophan, large doses of phenylalanine can cause severe amino acid imbalances and may be toxic.

Vitamins are an interesting subject because not all vitamins that are dietary essentials for one species are dietary essentials for other species. Vitamin C, or ascorbic acid, is a good example. Humans, non-human primates, guinea pigs, and rainbow trout have a dietary requirement for vitamin C because it can not be synthesized by the body. It is not a dietary essential for horses. Horses can synthesize vitamin C in their bodies. Moreover, the National Research Council's (NRC's) Nutrient Requirements of Horses states that horses do not absorb dietary vitamin C to any great extent. Some recent studies have indicated that older, geriatric horses may not be able to synthesize enough vitamin C to meet their requirements, but this has not been suggested for any other class of horse. Vitamin C, as well as various bioflavonoids, are often promoted to stop bleeding in racehorses. It has not been proven effective to stop bleeding and would be considered an unapproved drug for this purpose.

Another vitamin often promoted for use in horse diets is biotin, a B vitamin, which is a dietary essential for humans, pigs, chickens, dogs, and cats, among others. The horse's requirements for biotin, as for most of the B vitamins, should be met by bacterial synthesis in the cecum and large intestine with sufficient amounts absorbed to supply the animal's requirements without the need for dietary supplementation. The NRC's 1989 publication "The Nutrient Requirements of Horses" does not list a dietary requirement for biotin. No controlled studies have been published that establish a dietary biotin requirement above that supplied by intestinal synthesis. Some have theorized that biotin will promote hoof growth based on the fact that, in animals that have been shown to have dietary biotin requirements, a biotin deficiency is characterized by poor hoof growth. However, FDA is not aware of any data in peer-reviewed scientific journals that indicates that biotin has an effect on hoof growth in horses. Biotin products that make claims for increased or improved hoof growth are unapproved food additives.

Herbs and plant extracts are also marketed as feed supplements. Many herb products are marketed as sedatives. While many herbs are GRAS as spices, natural seasonings, or flavorings and are probably not unsafe to feed to horses, products often contain herbs that are not considered GRAS. There are no scientific data in horses on the safety and usefulness of herb products. Most information available on these products is anecdotal. Generally, the levels of the natural constituents in herbs can vary greatly as a result of the parts of the plant harvested, the growth stage of the plant at harvest, and processing methods. Herbs also contain chemicals that can be harmful, such as certain alkaloids. Toxicities have been associated with comfrey and chaparral in humans, and horsetail and snakeroot are known to be toxic to horses.

Advice for Horse Owners

While many of the products mentioned above are unlikely to do anything to benefit horses, they may be found in local feed or tack shops. These products are not removed from the market because most of FDA's limited

resources must be focused on products or incidences that pose a known hazard to human or animal health. Thus, FDA does not always have the time or resources to take enforcement action against products that are more fraudulent than dangerous. This is also true of feed programs administered by State governments. Therefore, horse owners must protect themselves from fraudulent products. Horse owners should be aware of the following signs when considering purchasing feed supplements.

First, they should look for disclaimers on the label or promotional material that read: "This is not a drug," and then other statements on the label claim that the product prevents, mitigates, treats, or cures a disease. The FDA does not allow the use of disclaimers on approved products. So, if the product has such a disclaimer, it is not approved. These types of products may be indirectly unsafe to horses, if owners are trying to treat their own horses rather than seeking advice from their veterinarian.

Second, owners should look for exaggerated claims for a product or products that are too good to be true. These are products that may solve a variety of problems, make horses win at shows, improve mental attitude, etc.

Third, horse owners should look for statements on products that use scare tactics. For example, products that claim that a horse has been suffering from a deficiency for years and owners never knew it. Other products may claim that they are totally unique and unlike any other feed supplement on the market and that it contains vitamin X or a new special ingredient.

Lastly, horse owners should look carefully at the label and learn how to interpret them. All labels for feed supplements should have a statement that describes the intended use of the product, for example, a vitamin and mineral supplement. The label should also have a list of ingredients. Federal regulation requires that the ingredients be listed by the common or usual name in descending order of predominance by weight. The list of ingredients can also help owners distinguish between a poor quality supplement and a good quality one. For example, the relative availability of copper from copper oxide is very low and generally less than 10 percent when compared to the copper sulfate, which is highly available. Therefore, a poor quality supplement may list copper oxide as a source of copper.

Also, horse owners should look at the guaranteed analysis. For complete feeds, many States now require guarantees be given for crude protein, fiber, and fat; calcium; phosphorus; copper; selenium; zinc; and vitamin A. Guarantees should also be given for any other major nutrients in the feed or supplement that is emphasized in the labeling. For example, if a label states "Horse supplement X with Vitamin E," the vitamin E content of that supplement should be guaranteed on the labeling. In addition, quantities must be given in English units and there must be adequate directions for use on the label that can be practically followed. If the guarantees are not provided on a per serving basis, some simple calculations can provide owners with the amount per serving. Owners could then compare this figure to the daily requirement for that nutrient for the horse. Many times what looks like a great supplement may only provide 1 to 2 percent of the daily amount of a nutrient required by a horse!

An educated horse owner is the best horse owner. If horse owners have any questions about the safety or usefulness of a product, they should not hesitate to contact an equine nutritionist or their veterinarian. If horse owners still have questions, they may write to the Center for Veterinary Medicine.