

VII. DIETARY SUPPLEMENTS IN RELATION TO OTHER FDA-REGULATED PRODUCTS

Dietary supplements generally are regulated as a sub-category of foods. As such, dietary supplements must comply with many of the regulatory requirements applicable to all foods, as well as the specific regulatory requirements applicable to dietary supplements. For example, many of the nutrient content claims authorized by FDA apply to all foods, including dietary supplements.

Although other terms, such as “nutraceuticals” and “functional foods,” may be used in the marketplace, such terms are not defined by FDA and have no regulatory meaning. FDA recognizes no class of products called “nutraceuticals” or “functional foods.” The product categories recognized by FDA are: food (including conventional foods, dietary supplements, infant formula, foods for special dietary use, medical foods and animal feed), drugs, biologics, cosmetics and medical devices. See, e.g., FDA, *Draft Guidance for Industry: Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration* (December 2006). It is essential to know which regulatory category a product falls under before marketing it.

In the case of animal products, FDA’s interpretation of the DSHEA is that it was not intended and does not apply to animal feed, including pet food. Accordingly, FDA does not recognize dietary supplements for animals. 61 Fed. Reg. 17706 (April 22, 1996). Products marketed as “feed supplements” are regulated as either foods or animal drugs, depending on their intended use.

The following chapters provide additional detail on these and other matters pertaining to U.S. regulation of dietary supplements.