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Dietary Supplements- Regulatory and Testing Requirements

A dietary supplement is a product taken orally that contains a dietary ingredient intended to supplement the diet. The dietary ingredients in these products may include vitamins, minerals, herbs or other botanicals, amino acids and substances such as enzymes, organ tissues, glandulars and metabolites. Dietary supplements can also be extracts or concentrates and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form, the Dietary Supplement Health and Education Act of 1994 (DSHEA) places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires that every supplement be labeled a dietary supplement (FDA - Overview of Dietary Supplements).

The FDA regulates dietary supplements as foods, but they are regulated differently from other foods and drugs. Supplement ingredients sold before October 1994 are not required to be reviewed by the FDA for their safety before they are marketed because they are assumed to be safe based on their history of use by humans. A new dietary ingredient (NDI) is a dietary ingredient that was not sold before October 1994. The FDA requires specific safety information from a company wishing to market a product as a dietary supplement that contains a new dietary ingredient. The company must notify the FDA of their intent to market a dietary supplement containing a new dietary ingredient and provide reasonable evidence that the product is safe for human use. On July 1, 2011, the FDA issued a draft guidance related to NDIs intended to assist the industry with deciding when a premarket safety notification for a dietary supplement containing an NDI is necessary.

Companies can only make certain claims about their product. The label may contain one of three types of claims: a health claim, a nutrient content claim or a structure/function claim. A

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health claim describes how a food, food component or dietary supplement ingredient can reduce the risk of disease or a health-related condition. A nutrient content claim describes the relative amount of a nutrient in the product. A structure/function claim describes how the product may affect the organs or systems of the body. These do not require FDA approval, but the company must provide the FDA with the text of the claims within 30 days of putting the product on the market. The labels must also include a disclaimer that reads, “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.” If the FDA can prove that the product is not safe, they can restrict the product’s use or even remove it from the market.

Labeling of the dietary supplement is required to be truthful and not misleading. It is required to include the name of the product, including “supplement” or a statement that the product is a supplement, the net quantity of contents, name and place of business or manufacturer, packer or distributor, directions for use, the serving size, list of dietary ingredients, amount per serving size and percent of Daily Value (%DV). If the dietary ingredient is a botanical, the scientific or common (standardized in *Herbs of Commerce, 2nd Edition*) name of the plant and the name of the part used must be included on the label. If the dietary ingredient is a proprietary blend, the total weight of the blend and the components of the blend in order of weight must be included on the label. Non-dietary ingredients, including fillers, artificial colors, sweeteners, flavors or binders must also be listed on the label by weight in descending order of predominance.

Testing of dietary supplements is much less stringent than that of products with actives in them (i.e. OTCs and prescription medications). Expiration dating of dietary supplements is not required by the FDA, but if the product has an expiration date on it, stability studies are required. Dietary supplement manufacturers are required to comply with current Good Manufacturing

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Practices (cGMPs) and raw materials must undergo identity testing to ensure their quality and purity. The majority of testing which a dietary supplement must undergo is determined by the label claims. Microbial testing is often performed to ensure that the product is free from microbial contaminants.

References:

- Alan Kurtzberg, Quality Manager
- NIH Office of Dietary Supplements
- FDA's Overview of Dietary Supplements
- FDA's 21 CFR Title 111
- Chrystal Chase, Quality Control

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