OREGON DEPARTMENT OF AGRICULTURE

Food Safety Program
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Dietary Supplements Guidance

What are Dietary Supplements?

A dietary supplement (defined in Food Drug & Cosmetic Act – 201(ff)) means a product (other than tobacco) intended to supplement the diet. It must:

- Be taken by mouth in a form that can be ingested (i.e. powder, capsule, tablet, liquid, gummy, soft gel etc.)
- Contain one or more "dietary ingredient"
- Not be represented for use as a conventional food or meal replacement
- Not include approved or investigational drugs
- Be labeled as a dietary supplement (the label must have a statement on the front of the product identifying it as a "dietary supplement" or similar descriptive term, e.g., "herbal supplement" or "calcium supplement")

Common supplements include:

- Vitamins (such as multivitamins or individual vitamins like vitamin D and biotin).
- Minerals (such as calcium, magnesium, and iron).
- Botanicals or herbs (such as echinacea, kava, golden seal, and ginger).
- Botanical compounds (such as caffeine, ginko biloba extract, green tea extract, and curcumin)
- Amino acids (such as tryptophan and glutamine).
- Live microbials (commonly referred to as "probiotics").

Food Safety Regulations and Basic FDA's Requirements for Dietary Supplements

To manufacture a dietary supplement in Oregon, you are required to be licensed and inspected by ODA Food Safety Program as a Food Processing Establishment. In addition to the standard food processing establishment requirements, firms that manufacture, package, label, or hold a dietary supplement are subject to 21 CFR Part 111, current Good Manufacturing Practices in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.

Firms that are subject to 21 CFR Part 111 must implement a system of production and process controls that cover all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR Part 111.55).

Quality *means that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.*
Quality Control *means a planned and systematic operation or procedure for ensuring the quality of a dietary supplement (21 CFR Part 111.3).*

- You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch (21 CFR Part 111.205).
- You must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR Part 111.70).
- You must determine whether the specifications you establish are met (21 CFR Part 111.73) through testing dietary ingredient(s) and finished dietary supplement product.

- You must establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing (21 CFR Part 111.103).
- You must prepare a batch production record every time you manufacture a batch of a dietary supplement. The batch production record must include complete information relating to the production and control of each batch, and accurately follow the appropriate master manufacturing record (21 CFR Part 111.255).

Labeling Requirements for Dietary Supplements

Five statements are required on the containers and packages of dietary supplement:

- The statement of identity (name of the dietary supplement)
- The net quantity of contents statement (amount of the dietary supplement)
- The nutrition labeling
- The ingredient list
- The name and place of business of the manufacturer, packer, or distributor

The nutrition label for a dietary supplement is called a "Supplement Facts" panel that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. Two exemptions for small businesses and low-volume products are available only if the products' labels bear no claims or other nutrition information. See labeling references below.

FDA Dietary Supplement Labeling Guide
21 CFR Part 101 Food Labeling
ODA Food Labeling Handout

Claims for Dietary Supplements

The types of claims that can be made on the labels of dietary supplements and drugs differ. A product intended to diagnose, treat, prevent, cure, or alleviate the symptoms of a disease is a drug, and therefore subject to all requirements that apply to drugs. For example, dietary supplements may not make implicit or explicit statements such as “treats arthritis”, “cures cancer” or “for obesity”.

The label of a dietary supplement product may contain one of three types of claims (Dietary Supplement Labeling Guide: Chapter VI. Claims):

- **Health Claim**: A Health Claim describes a relationship between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition. Details and a list of approved health claims is available on the FDA website by searching for “SSA Health Claims.” The Center for Food Safety and Applied Nutrition (CFSAN) can also provide information, 888-723-3366.
- **Nutrient Content Claim**: A Nutrient Content Claim describes the relative amount of a nutrient or dietary substance in a product.
- **Structure/Function Claim**: A Structure/Function Claim is a statement describing how a product may affect the organs or systems of the body and cannot mention any specific disease. Product labels containing structure/function claims 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.”

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