Washington State Department of Agriculture

FOOD SAFETY PROGRAM
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Dietary Supplements

According to the Food and Drug Administration (FDA), Dietary Supplements:

- Are labeled as a Dietary Supplement.
- Are intended to add or supplement the diet.
- Are ingested, not inhaled or used as a topical cream.
- Are not represented as the sole item of a meal or the diet.
- Are different from conventional foods and are not represented as a conventional food.
- Include at least one of the following: Vitamins (such as Vitamin C), Minerals (such as Calcium), Botanicals or herbs (such as echinacea), Botanical compounds (such as caffeine), Ammino Acids (such as glutamine), and Probiotics.
- Come in many forms: liquids, gummies, bars, powders, tablets, capsules, soft gels, and gel caps.

Dietary Supplement (DS) labels require:

1. The statement of identity (the product needs to be identified as a dietary supplement).
2. The net quantity of contents statement (amount of the dietary supplement).
3. The Supplement Facts Panel.
4. The ingredient list: "ingredient" refers to the compounds used in the manufacture of the DS.
5. The name and place of business of the manufacturer, packer, or distributor.

The FDA regulates dietary supplements differently from conventional foods. The FDA has created specific Dietary Supplement Current Good Manufacturing Practices (cGMPs) that require manufacturers to have written procedures and a robust quality control program to ensure the Dietary Supplements are manufactured to high standards of identity, purity, strength, and composition.

A Food Processor's License is required if you process dietary or nutritional supplements in Washington State. Only dietary supplements **that do not make health claims** can be licensed with WSDA.

If a supplement product is intended to treat, diagnose, cure, or prevent diseases, it is a Drug, even if it is labeled as a dietary supplement. The FDA requires premarket approval of Drugs before they can be sold.

The Nutrition Labeling and Education Act (NLEA) directed the FDA to issue regulations providing for the use of health claims. All health claims must undergo review by the FDA through a petition process.

AGR6-2509-035 (New 2509) *Do you need this publication in an alternate format? Contact WSDA at (360) 902-1976 or TTY Relay 800-833-6388.*

Health claims:

- Contain the elements of a substance and a disease or health-related condition;
- Are limited to claims about disease risk reduction;
- Cannot be claims about the diagnosis, cure, mitigation, or treatment of disease; and are required to be reviewed and evaluated by the FDA prior to use.
- The FDA determines what health claims are allowed on a label, not WSDA.

Structure/function claims:

- Statements that describe the role a dietary ingredient plays in maintaining the body's normal, healthy structure or function.
- Examples: "Calcium supports strong bones.", "Vitamin C supports immune function."
- Structure/function claims are allowed on Dietary Supplement labels only with the included disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." (21 CFR Part 101.93)

How to get licensed as Dietary Supplements manufacturer:

- ☑ Submit Food Processor application.
- ☑ Meet Food Processor facility requirements.
- ☑ Meet Dietary Supplement labeling requirements.
- ☑ Do not make any health claims on your labels.
- ☑ Include required disclaimer if you make structure/function claims.
- ☑ Include documentation that each dietary ingredient used in your process is safe for human consumption.

Manufacturers are responsible for the safety of their products.

WSDA can't assess every potential combination of ingredients to ensure product safety. This is the manufacturer's responsibility. Dietary Supplement manufacturers must understand the safety of each ingredient used in their products. This assessment must include how potential interactions with other ingredients could affect the safety of these products.

Manufacturers must obtain documentation of dietary ingredient acceptability.

For any ingredients not approved for use in conventional food products, the manufacturer must provide documentation to support that the FDA recognizes the safe use of each dietary ingredient in the supplement. Two references a firm can use include but are not limited to: FDA Food Ingredient and Packaging Inventory (cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?cat=FoodIngredientsPackaging) and NIH Dietary Supplement Label Database (dsld.od.nih.gov/dsld/).

Helpful Links

- PART 111—Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- FDA 101: Dietary Supplements
- NIH Dietary Supplement Label Database
- FDA Dietary Supplement Labeling Guide
- FDA Food Ingredient and Packaging Inventory
- Guidance for using these references