SELLING HERBAL OR DIETARY SUPPLEMENTS

FACT SHEET 39

Herbal and dietary supplements are products that are ingested and include dried herbs, teas, tinctures, capsules, and tablets. These supplements have a specific federal and state definition and must meet the same regulatory requirements for any processed food, as well as additional requirements listed below.

This fact sheet includes information on:

- Definition of "dietary supplements."
- Food safety regulations for dietary supplements.
- Making health claims.
- Labeling requirements for dietary supplements.

Selling fresh culinary herbs is regulated differently than selling herbal and dietary supplements. Please see the "Selling Herbs" fact sheet for information on culinary herbs.

Definition of "Dietary Supplements"

The State of Washington follows the Food and Drug Administration (FDA) definition of "dietary supplements." This means that in Washington State, a dietary supplement is a product (other than tobacco) that is:

1. Intended to supplement the diet, that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used by humans to supplement the diet by increasing the total daily intake; or a concentrate, metabolite, constituent, extract, or combination of these ingredients; and is
2. Intended for ingestion in pill, capsule, tablet, softgel, gelcap, powder, or liquid form.

Products made from cannabis or hemp do not fall under the definition of dietary supplements and are regulated separately in Washington State. See the fact sheet on "Selling Marijuana, Hemp, and Cannabis Products."

Food Safety Regulations for Dietary Supplements

WSDA Food Processor License

Manufacturing herbal or other dietary supplements, including tinctures, requires a WSDA Food Processor License and a facility. Please see the "WSDA Food Processor License and Facilities" fact sheet. In addition, to the standard processing and labelling requirements for processed foods covered by the WSDA Food Processor License, dietary and herbal supplements have special labelling and marketing requirements from the FDA. By law, a business that manufactures and sells a dietary supplement is responsible for determining that the product is safe before it is marketed. Private firms and some public universities can help with product safety testing. For an overview see the FDA's "101: Dietary Supplements" information on their website, fda.gov.

Licensing for Alcohol-Based Tinctures and Extracts

When the final use of a high alcohol tincture can be expected to dilute the alcohol content down to 0.5 percent or less, the product is considered a non-alcohol product that can be made with a WSDA Food Processor License. For example, a vanilla flavoring may contain 35 percent alcohol; however, when used it will be diluted down to under 0.5 percent content in the product it is used as a flavoring in. Tinctures and herbal extracts may have 20-90 percent alcohol content; however, as used, the alcohol content should be 0.5 percent or less. Please contact the WSDA Food Safety Program, 360-902-1876, or foodsafety@agr.wa.gov and the Washington State Liquor and Cannabis Board, 360-664-1600, to confirm regulatory requirements for your specific products and processes.

Making Health Claims

Washington State law complies with federal law (the Food, Drug, and Cosmetic Act and the Trade Commission Act) that expressly outlaws the false advertisement of food, drugs, devices, and cosmetics. For details, please refer online to the Washington State Intrastate Commerce in Drugs and Cosmetics code (Chapter 69.04 RCW) which outlines the regulations governing the sale of dietary supplements, apps.leg.wa.gov/RCW.

Producers need to be very careful about making any health claims. Washington State does not allow any claims to be made about the use of herbal and dietary supplements to diagnose, prevent, mitigate, treat, or cure a specific disease. For instance, statements such as "cures cancer" or "treats arthritis" may not be used. Find more information about health claims by searching the FDA website, fda.gov for "Questions on Health Claims in Food Labelling".

The FDA has authorized use of some health claims that may be used if the dietary supplement qualifies to bear the claim. These authorized health claims meet the Significant Scientific Agreement (SSA) Standard, meaning there is enough agreed-upon scientific evidence to support a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition. For example, "calcium reduces the risk of osteoporosis." Details and a list of approved health claims is available on the FDA website, fda.gov, by searching for "SSA Health Claims." The Center for Food Safety and Applied Nutrition (CFSAN) can also provide information, 888-723-3366.

Labeling Requirements for Dietary Supplements

Dietary supplements must meet the same labeling requirements as other processed foods plus additional specific requirements for dietary supplements; they must be identified as a "dietary supplement" on the product label, which also must identify serving size, calories, dietary ingredients, and supplement facts. These federal regulations are specified in FDA Title 21 CFR Part 111 "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," which can be found online by searching the FDA website. The FDA's online "Dietary Supplement Labeling Guide: Chapter 1" includes labeling guidelines and examples.

For more information, please call (360) 902-1876, email foodsafety@agr.wa.gov or visit agr.wa.gov, for the Food Safety Program.

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