



Interpreting Product Labels

1. Brand name
2. Product/herb name
3. Herbal products and other “dietary supplements” may make “statements of nutritional support,” often referred to as “structure/function claims,” as long as they are truthful and not misleading, are documentable by scientific data, and do not claim to diagnose, cure, treat, or prevent any disease, and carry a disclaimer on the product label to this effect. The disclaimer must also note that FDA has not evaluated the claim. The product manufacturer must also notify the FDA of the structure/function claim within 30 days of bringing the product to market. According to current FDA regulations, examples of acceptable structure/function claims include “supports the

immune system” and “supports a healthy heart,” while claims such as “helps treat the common cold” and “helps prevent heart disease” are considered unacceptable, as these are considered drug claims. Thus “helps maintain urinary tract health” is acceptable while “helps prevent urinary tract infections” is not.

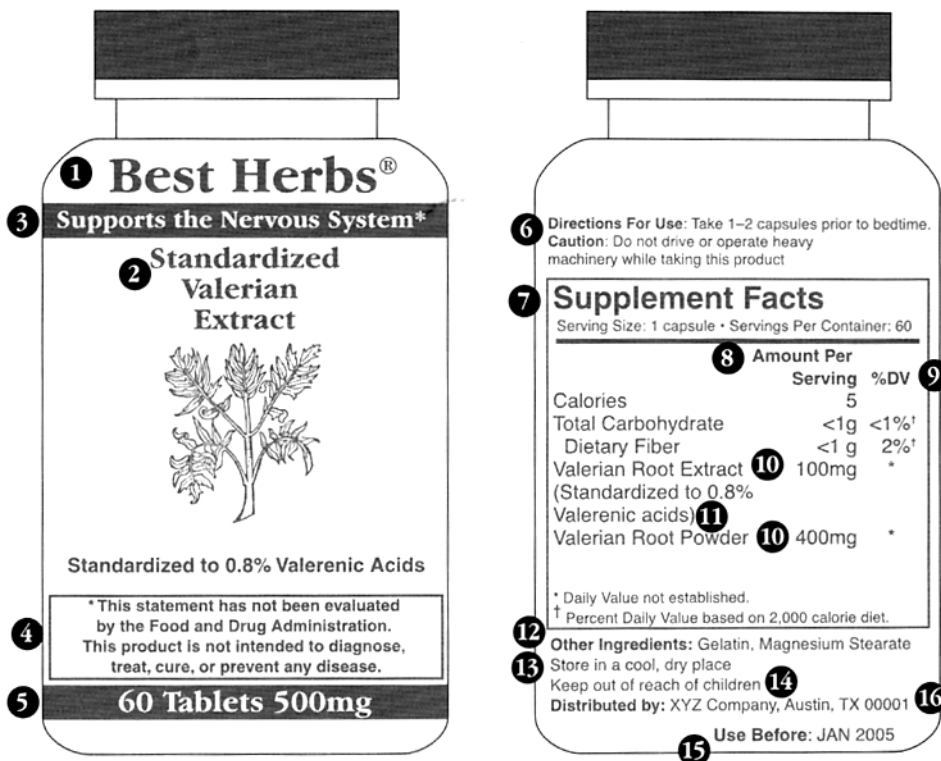
4. A structure/function claim requires this disclaimer when it appears on the label of a dietary supplement, as well as in any brochures or advertising. The disclaimer must be in bold type and in a box.
5. Number of tablets, capsules, and net weight of each in package.
6. Directions for Use and Cautions.

Items 7-10 are part of the “Supplement Facts Panel”

7. “Serving Size” is the suggested number of tablets, capsules, softgels, tea bags, liquid extract, or tincture to take at one time.
8. “Amount per Serving” first indicates the nutrients present in the herb and then specifies the quantity. The following items must be declared if in excess of what can legally be declared as zero: calories, fat, carbohydrates, sodium, and protein. In addition, the following nutrients must also be declared if present in quantities exceeding what can legally be declared as zero: vitamins A, C, D, E, K, B-1, B-2, B-3, B-6, B-12, folic acid, biotin, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium. Most herbal products contain negligible amounts of these nutrients.

9. “Percent Daily Value” (%DV) indicates the percentage of daily intake provided by the herb. An asterisk under the “Percent Daily Value” heading indicates that a Daily Value is not established for that dietary ingredient.

10. Herbs should be designated by their standardized common names as listed in the book *Herbs of Commerce*, published in 1992 by the American Herbal Products Association. If the common name is not listed in *Herbs of Commerce*, then the common name must be followed by the herb’s Latin name. The plant part must be listed for each herb. The amount in milligrams of each herb must be listed unless the herbs are grouped as a proprietary blend—then only the total amount of the blend need





be listed. For herbal extracts, the following information must be disclosed: 1. the ratio of the weight of the starting material to the volume of the solvent (even for dried extracts where the solvent has been removed, the solvent used to extract the herb must be listed); 2. whether the starting material is fresh or dry; and 3. the concentration of the botanical in the solvent.

11. Standardization. If a product is chemically standardized, the product label may list the component used to measure standardization (e.g., ginsenosides in Asian ginseng, valerenic acids in valerian, etc.) and the level to which the product is standardized (e.g. 4% ginsenosides). Therefore, if a product contained 100 mg of Asian ginseng extract per capsule and the extract was standardized to 4% ginsenosides, one capsule would contain 4 mg of ginsenosides. In most, but not all, cases, the component used to measure standardization is bioactive, although the standardization component may not be responsible for the intended primary activity of the herbal supplement, other active compounds may be responsible. Products can also be standardized to “marker compounds” for purposes of quality control. Those markers may or may not be active.
12. A list of all other ingredients, in decreasing order by weight, must appear outside the Supplement Facts box. In herb formulas containing multiple herbal ingredients, the herbs must be listed in descending order of predominance.
13. The proper location for storage of herbal products is typically labeled as a cool, dry place.
14. All herbal products and other dietary supplements should be kept out of the reach of children.
15. The herb should be used before the expiration date for maximum potency and effectiveness. Expiration dates are often arbitrarily established by the manufacturer, regardless of the ingredients and their relative stability. Such dates are routinely set at two years from the date of manufacture of the finished dietary supplement, although this period may be longer or shorter depending on the manufacturer’s policies, stability testing, dosage form, and other variables.
16. The product must list the manufacturer or distributor’s name, city, state, and zip code.