Labeling and Packaging Specs

A Vitamin Consultancy eBook

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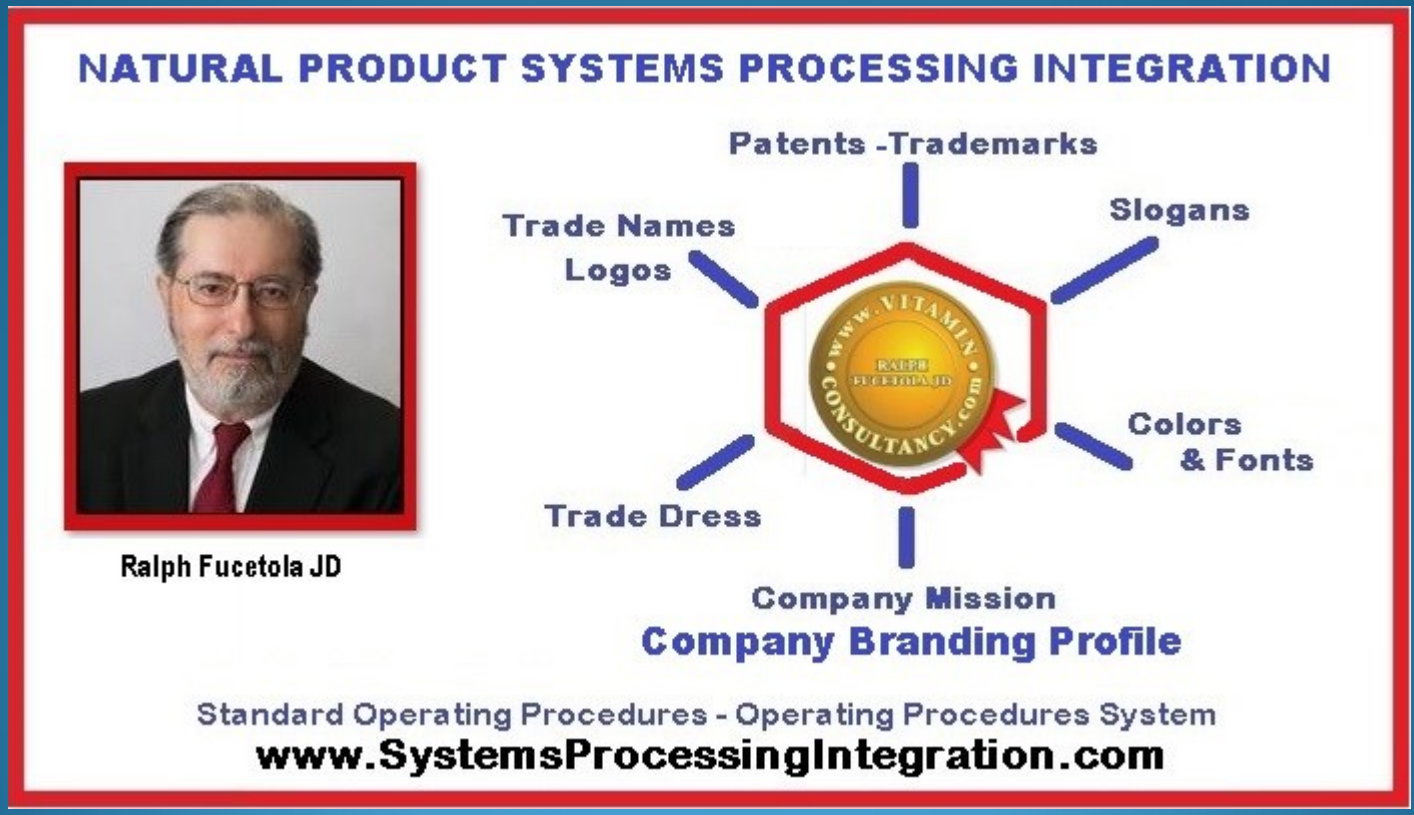

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This presentation is based upon Standard Operating Procedure (SOP) #25 in the Vitamin Consultancy SOP format.

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* Technical details of label formatting: font sizes, line sizes, etc.

Labeling and Packaging Specifications

- This presentation covers specifications for Dietary Supplement Packaging and Labeling under 21 CFR §111.70 and §111.75.

  Requires the keeping of a **Packaging and Labeling Log** as a Record of batches of labeling and packaging.

- [1] Specifications for dietary supplement labels (label specifications) includes keeping records that link specific batches of labels with specific batches of the product.

- [2] Specifications for packaging that may come in contact with dietary supplements (packaging specifications).

[1] Label Specifications:

- (1) The labeling shall meet all DSHEA content requirements, including:

  - Statement of Identity ("Dietary Supplement")
  - Lawful Product Names
  - Standard Statutory Disclaimer
  - Permitted Directions
  - Necessary Warnings (including Statutory Disclaimer)
  - Supplement Facts Box
  - Only DSHEA-grandfathered ingredients (or FDA approved NDIs - New Dietary Ingredients)

1. Main Panel Must Include:

- A. Name of Product: _____ (followed by the ® or TM)
- B. Total number of capsules/pills in bottle
- C. The term "Dietary Supplement" or "_____ Supplement"

- Identify a dietary supplement by use of the term "dietary supplement" as part of the statement of identity, except that label may delete the word "dietary" and replace it with the name of the dietary ingredient(s) in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredient(s) in the dietary supplement product (e.g., herbal supplement with vitamins).

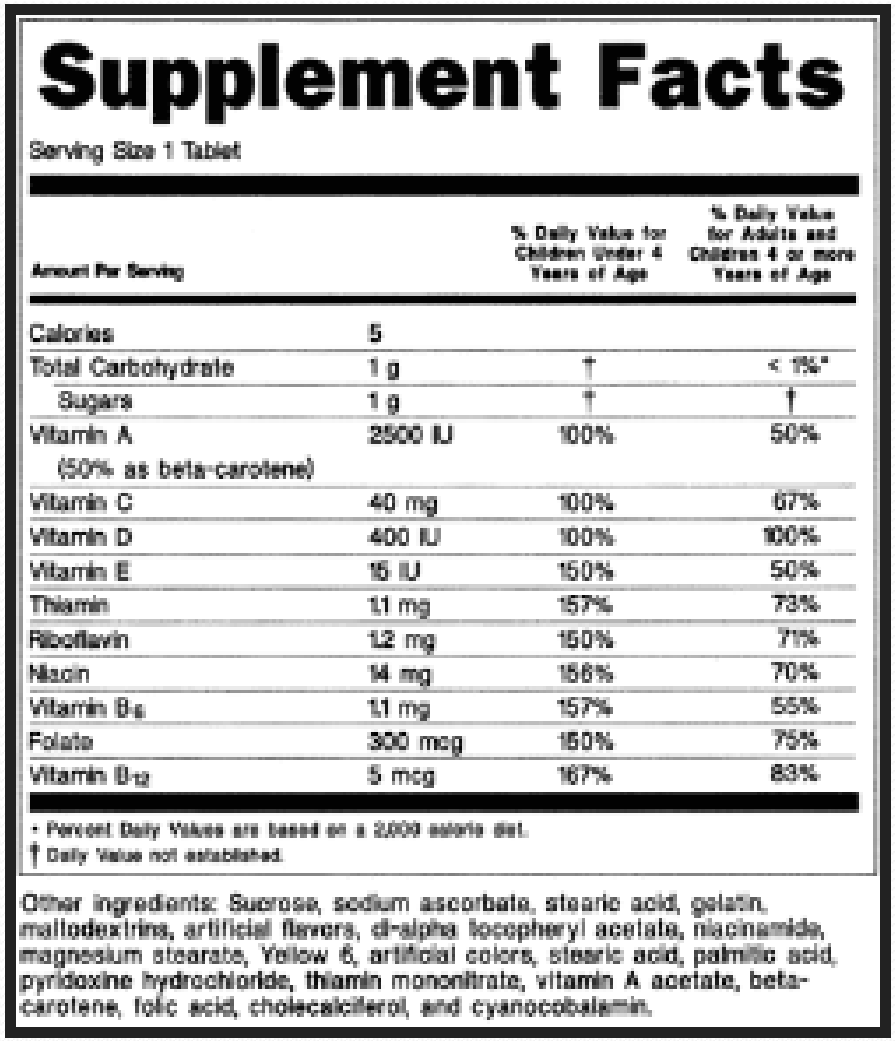
If a Proprietary Blend is Used:

- Identify proprietary blends by use of the term "Proprietary Blend" or an appropriately descriptive term or fanciful name.
- On the same line, list the total weight of all "other dietary ingredients" contained in the blend.
- Indented underneath the name of the blend, list the "other dietary ingredients" in the blend, either in a column or linear fashion, in descending order of predominance by weight.
- These ingredients should be followed by a symbol referring to the footnote "Daily Value Not Established."

- Dietary ingredients having RDIs or DVs **must** be listed above and separately from the Proprietary Blend (in alphabetical order, starting with the vitamins) and the individual weights declared. 21 CFR 101.36(b)(2) and (c)

2. The Supplement Facts Box

The Right Side Panel Supplement Facts Box Sample



Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

Also listed on the Right Side Panel: Name and contact information for the Company

3. Directions, Warnings and Disclaimers.

The Left Side Panel:

- Dietary Supplements must include Directions since such food products are *deemed safe if used as directed*. Standard Warnings and Disclaimers are also needed, including the Statutory Disclaimer,

  "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

- Directions: "For use as a dietary supplement, take…" [*Never* use the word "dose."]

- Generally, include other standard disclaimers, such as, "Do not use if safety seal is broken. Keep out of reach of children. Store in a cool dry area at room temperature. Not for use by pregnant or lactating women." If Allergens present, must include Allergy Warning.

Allergens

- If product contains common allergens, it needs to include an Allergy Warning as well.
- The Warning stated: “Contains: [List]”
- The common allergens that must be listed are:
  - Milk
  - Egg
  - Peanut
  - Tree nut (e.g., almonds, walnut, pecans, cashews, pistachios)
  - Wheat
  - Soy
  - Fish (e.g., bass, flounder, cod)
  - Shellfish (e.g., crab, shrimp, scallop, clams)

  Must state the type of nuts or fish

”The word "Contains" with a capital "C" must be the first word used to begin a "Contains" statement. (The use of bolded text and punctuation within a "Contains" statement is optional.)”

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4

[2] Packaging Specifications:

- Packaging that may come into contact with dietary supplements must be:
  - (1) safe and suitable for its intended use and
  - (2) must not be reactive or absorptive or otherwise affect:
  - (a) the safety or
  - (b) the quality of the dietary supplement.
- [3] The specification for the packaging and labeling of the finished packaged and labeled dietary supplements shall ensure that the staff members tasked with the packaging and labeling used the specified packaging and that applied the specified label.

Packaging and Labeling Log

- (1) The staff members so tasked shall note in the Packaging and Labeling Log that, pursuant to 21 CFR § 111.75 (f) (2), the staff member initialing and dating the Log entry did conduct a

  [1] visual examination of the label and
  [2] review of the supplier's invoice, guarantee, or certification to determine that label specifications are met.

- (2) The staff members so tasked shall note in the Packaging and Labeling Log that, pursuant to 21 CFR § 111.75 (g) the staff member initialing and dating the Log entry did conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether

  [1] the specified packaging was used and
  [2] the specified label was applied to the correct product.

Format for Log

Packaging and Labeling Log

	Date	Product	Batch #	Notes	Initials
1.					
2.					
3.					

Addendum - 1

- **Addendum #9 – Labeling and Packaging Specifications - SOP #25**

- FDA REGULATION ON LABEL DETAILS
  Sec. 101.36 Nutrition labeling of dietary supplements.

- ITEMS 'INSIDE THE BOX' FOR THE 'SUPPLEMENT FACTS' BOX:

- SERVING SIZE -- The subheading 'Serving Size' shall be placed under the heading 'Supplement Facts' and aligned on the left side of the nutrition label. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as 'tablets,' 'capsules,' 'packets,' or `'teaspoonfuls.'

- SERVINGS PER CONTAINER -- The subheading 'Servings Per Container' shall be placed under the subheading 'Serving Size' and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

- AMOUNT PER SERVING / EACH CAPSULE CONTAINS -- (A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading 'Amount Per Serving.' When the quantitative amounts by weight are presented in a separate column, the heading may be centered over a column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. A heading consistent with the declaration of the serving size, such as 'Each Tablet Contains,' or 'Amount Per 2 Tablets' may be used in place of the heading 'Amount Per Serving.' Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term 'Serving.' The names of dietary ingredients that are declared under shall be presented in a column aligned on the left side of the nutrition label. Dietary ingredients shall be listed according to the nomenclature specified in Sec. 101.9 or in paragraph (b)(2)(i)(B)(2) of this section PLEASE NOTE 'PROPRIETARY BLEND' INFORMATION BELOW

- The percent of the Daily Value of all dietary ingredients shall be listed - the quantitative amount by weight and the percent of Daily Value may be presented on a 'per unit' basis in addition to on a 'per serving' basis, as required in paragraph (b)(2)(ii) of this section. This information shall be presented in additional columns and clearly identified by appropriate headings.

Addendum 2

- These amounts shall be expressed using metric measures in appropriate units (i.e., 1,000 or more units shall be declared in the next higher set of units, e.g., 1,100 mg shall be declared as 1.1 g).

- The constituents of a dietary ingredient may be listed indented under the dietary ingredient and followed by their quantitative amounts by Weight. Other dietary ingredients shall bear a symbol (e.g., an asterisk) in the column under the heading of '% Daily Value' that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement 'Daily Value not established,' except that when the heading '% Daily Value' is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

- PROPRIETARY BLEND: A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term 'Proprietary Blend' or other appropriately descriptive term or fanciful name and may be highlighted by bold type. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

- Nutrition information specified in this section shall be presented as follows:

- (1) The title, 'Supplement Facts,' shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be bolded to distinguish them from other information.
- (2) The nutrition information shall be enclosed in a box by using hairlines.
- (3) All information within the nutrition label shall utilize:
- (i) A single easy-to-read type style,
- (ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical,
- (iii) Upper- and lowercase letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches,
- (iv) At least one point leading (i.e., space between lines of text), and
- (v) Letters that do not touch.

- (4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., 'Amount Per Serving' and '% Daily Value') and for footnotes (e.g., 'Percent Daily Values are based on a 2,000 calorie diet').

Addendum 3

- (5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

- (6) A heavy bar shall be placed:

- (i) Beneath the subheading 'Servings Per Container' except that if 'Servings Per Container' is not required and, as a result, not declared, the bar shall be placed beneath the subheading 'Serving Size,'
- (ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and
- (iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

- (7) A light bar shall be placed beneath the headings 'Amount Per Serving' and '% Daily Value.'

- (8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iii) of this section.

- (9) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(10) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left.