

Supplement Facts – Self-Audit Checklist (most common errors)

- Does the “Supplement Facts” header run the full width of the box?¹ Adjust using IMAGE functions.
- Did you enter the Serving Size in customary US measures (with metric equivalent when needed)?²
- Did you enter the number of Servings per Container, if required?

Supplement Facts		
Serving Size 2 capsules		
Servings per Container 30		
Amount per Serving	% DV	
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Proprietary Blend	100 mg	†
<i>Echinacea angustifolia</i> (root), Turmeric Root Extract.		
Omega 3 Fatty Acids	200 mg	†
† Daily Value (DV) not established.		
Other ingredients: Fish oil, softgel capsule (bovine gelatin, water).		
Contains Fish (anchovies, sardines, tuna).		

- Did you enter the correct Amount per Serving (including unit of measure) for each ingredient?
- Nutrients or ingredients are ONLY declared when greater than insignificant amounts as shown in the table below. Note: You will see warning messages in the app if the amounts are insignificant, and you should correct them manually.³ For example, an amount equivalent to zero (<5 calories) should be removed from the label, as you cannot declare zero calories in Supplement Facts.

Nutrient	Insignificant Amount: DO NOT declare if less than...
Calories	<5 calories
Fat - Saturated fat - <i>Trans</i> fat	<0.5 g
Cholesterol	<2 mg
Total carbohydrate – Fiber - Sugar	<0.5 g
Protein	<0.5 g
Vitamins – Minerals (except Sodium)	<2% Daily Value
Sodium	<5 mg

¹ 21 CFR 101.36(e)(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.

² 21 CFR 101.36(b)(1) Serving size. (i) ... 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."

(ii) 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. (e.g. when serving size is 1 capsule, net contents equals the number of servings)

³ 21 CFR 101.36(b)(2) ...Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

FDA Examples: <https://www.fda.gov/files/food/published/High-Resolution-Examples-of-Different-Supplement-Facts-Labels-in-the-New-Format.pdf>

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- Are the source ingredients included for each dietary ingredient, either within the Supplement Facts box OR in the Ingredients (or Other ingredients) list?⁴

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Servings per Container 30		
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† Daily Value (DV) not established.		
Other ingredients: Fish oil, softgel capsule (bovine gelatin, water).		
Contains Fish (anchovies, sardines, tuna).		

- If the product contains a Proprietary Blend, did you enter the amount of the blend per serving and each of the blend ingredients in order of predominance by weight?⁵
- For botanical ingredients, did you include the plant part, and the Standardized Common Name (SCN, as listed in Herbs of Commerce 2nd Ed. "HOC") OR use the Latin binomial, if not listed in HOC?
- Are other dietary ingredients (without a DV) declared by their common or usual names?⁶
- Did you include the capsule and any other ingredients (fillers, excipients, colors, flavors etc.)?
- Are major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, sesame, soybeans) declared?

⁴ 21 CFR 101.36(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words "as" or "from", e.g., "Calcium (as calcium carbonate)," except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Oriental ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with § 101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

⁵ 21 CFR 101.36 (c)(2) Dietary ingredients contained in the proprietary blend ...shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term "Proprietary Blend" or other appropriately descriptive term or fanciful name. (3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend

⁶ 21 CFR 101.36(b)(3) Information on dietary ingredients for which RDI's and DRV's have not been established. (i) Dietary ingredients for which FDA has not established RDI's or DRV's ...(referred to as "other dietary ingredients") shall be declared by their common or usual name when they are present in a dietary supplement...The quantitative amount by weight shall be the weight of the other dietary ingredient listed and not the weight of any component, or the source, of that dietary ingredient. These amounts shall be expressed using metric measures in appropriate units.