

Supplements Facts ≠ All the Facts

What the New Label Does – And Doesn't – Disclose

On March 23, 1999, dietary supplement companies will have made the transition from an "anything goes" label to a federally imposed label similar to the one now required for foods. Forever after, dietary supplements shipped in interstate commerce must have the new "Supplement Facts" label attached.

The following outline is a general guide to a purchaser of dietary supplements regarding what information the new "Supplement Facts" label must disclose. In addition, the existence of other pertinent information, not required to be disclosed by the new label, is also outlined.

The FDA labeling regulation requires ingredients designated as having a "Daily Reference Value" or a "Reference Daily Intake" to be listed in a specific order, with the same nomenclature, and with the percentage of Daily Reference Value delineated. Minerals must list their salt sources in a uniform format. Herbs and herbal extracts must be listed with their common name and Latin name as delineated by the American Herbal Products Association official listing "Herbs of Commerce," as well as the plant part which is used.

Under "Other Ingredients," just below the Supplement Facts box, you will find additives: Binders (to bind tablets together); Lubricants (to assist powder flow in manufacturing); Coatings (to coat tablets and permit easier swallowing); Colorings (cosmetic reasons); and Fillers (used to fill space).

The following is a list of many such additives grouped into general categories relative to their potential to cause allergic

Label demonstrating daily value and order in which nutrients must be listed.

Format 1. Nutrient listed, source listed under "Ingredients."

Supplement Facts
Serving Size: Eight Capsules

Eight Capsules Contain:	%DV
Vitamin A	5000 IU 100%
Vitamin C	60 mg 100%
Vitamin D	400 IU 100%
Vitamin E	30 IU 100%
Vitamin K	80 mcg 100%
Thiamine	1.5 mg 100%
Riboflavin	1.7 mg 100%
Niacin	20 mg 100%
Vitamin B6	2 mg 100%
Folate	400 mcg 100%
Vitamin B12	.6 mcg 100%
Biotin	300 mcg 100%
Pantothenic Acid	.10 mg 100%
Calcium	1000 mg 100%
Iron	18 mg 100%
Phosphorus	1000 mg 100%
Iodine	150 mcg 100%
Magnesium	400 mg 100%
Zinc	15 mg 100%
Selenium	70 mcg 100%
Copper	2 mg 100%
Manganese	2 mg 100%
Chromium	120 mcg 100%
Molybdenum	75 mcg 100%
Chloride	3400 mg 100%
Sodium	2400 mg 100%
Potassium	3500 mg 100%

Daily Value (DV)

Ingredients: Binders, coatings, colorings, fillers, excipients, etc.
Beta Carotene, Ascorbic Acid, Cholecalciferol, D alpha Tocopheryl, Phylloquinone, Thiamine HCl, Riboflavin, Niacin, Pyridoxine HCl, Folic Acid, Cyanocobalamin, Biotin, Calcium Pantothenate, Calcium Citrate, Iron Citrate, Dicalcium Phosphate, Potassium Iodide, Magnesium Citrate, Zinc Citrate, Sodium Selenite, Copper Citrate, Manganese Aspartate, Chromium Citrate, Molybdenum Citrate, Sodium Chloride, Potassium Chloride.

Callouts:

- Different title than food label
- Serving size is designated
- All nutrients listed on a "Per Serving" basis
- Weight listed is weight of ingredient, not weight of source of ingredient (e.g., amount of true Thiamine must be listed here. The source, HCl or Mononitrate, may be shown here in parentheses or below as an ingredient)
- FDA mandates uniform units of measure
- Ingredients not listed above are listed here
- Source of nutrients above can be listed here (For demonstration purposes only, these nutrients are listed in the same order as above, instead of in descending order of weight)

Editorial

Label demonstrating daily value and order in which nutrients must be listed.

Format 2. Nutrient listed, source listed in parentheses.

Different title than food label

Serving size is designated

All nutrients listed on a "Per Serving" basis

Weight listed is weight of ingredient, not weight of source of ingredient. (e.g., amount of true Thiamine must be listed here. The source, HCl or Mononitrate, may be shown here in parentheses or below as an ingredient)

FDA mandates uniform units of measure

Source of nutrient listed in parentheses

Ingredients not listed above are listed here.

Supplement Facts

Serving Size: Eight Capsules

Eight Capsules Contain:		%DV
Vitamin A (as Beta Carotene)	5000 IU	100%
Vitamin C (as Ascorbic Acid)	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E (as D-alpha Tocopheryl)	30 IU	100%
Vitamin K	80 mcg	100%
Thiamine (as Thiamine HCl)	1.5 mg	100%
Riboflavin (as Riboflavin)	1.7 mg	100%
Niacin (as Niacin)	20 mg	100%
Vitamin B6 (as Pyridoxine HCl)	2 mg	100%
Folate (as Folic Acid)	400 mcg	100%
Vitamin B12 (as Cyanocobalamin)	6 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (as Calcium Pantothenate)	10 mg	100%
Calcium (as Calcium Citrate)	1000 mg	100%
Iron (as Iron Citrate)	18 mg	100%
Phosphorus (from Dicalcium Phosphate)	1000 mg	100%
Iodine (from Potassium Iodide)	150 mcg	100%
Magnesium (as Magnesium Citrate)	400 mg	100%
Zinc (as Zinc Citrate)	15 mg	100%
Selenium (as Sodium Selenite)	70 mcg	100%
Copper (as Copper Citrate)	2 mg	100%
Manganese (as Manganese Aspartate)	2 mg	100%
Chromium (as Chromium Citrate)	120 mcg	100%
Molybdenum (as Molybdenum Citrate)	75 mcg	100%
Chloride (as Sodium Chloride)	3400 mg	100%
Sodium (as Sodium Chloride)	2400 mg	100%
Potassium (as Potassium Sulfate)	3500 mg	100%

Daily Value (DV)

Ingredients: Binders, coatings, colorings, fillers, excipients, etc.

or sensitivity reactions, impede absorption, or have an undesired physiological effect.

Universally tolerated, generally inert product additives:

Individual amino acids. Basic minerals – Calcium, Magnesium, etc., as Oxides, Carbonates, Phosphates or Organic Acid complexes, e.g., Calcium Citrate or Magnesium Aspartate, Ascorbate, Malate, etc., but not “Amino Acid Chelates,” which can contain partially digested protein instead of pure amino acids. Also, Titanium Dioxide (the white color used in some tablets and capsules), Silicon Dioxide (fumed Silica), Talc, and Silicates (Ca, Mg).

Generally well-tolerated product additives:

Cellulose as filler, binder, or coating, generally labeled as: Cellulose, Hydroxypropyl Methylcellulose, Ethyl Cellulose, Hydroxypropyl Cellulose, Microcrystalline Cellulose, and Croscarmellose Sodium. Also, Crospovidones, Bentonite, and Polysorbates.

Generally tolerated additives, with possibility of sensitive patient reaction:

Sodium Starch Glycolate, Starch, Mannitol, Sucrose, Acacia and other gums. Preservatives such as Benzoates, Parabens, Sorbates and Propionates. Antioxidants such as BHT and BHA. Coatings such as Pharmaceutical Glaze and Zein – (See Coatings in “NAME DECEPTION”).

Additives utilized for economy or appearance, presenting potential patient problems:

Lactose, Corn Starch, Sucrose, all FD&C dye lakes, all organic coloring agents.

Additives utilized in virtually all tablets and most capsules* for lubrication which impede absorption and present the possibility of patient sensitivity:

Stearic acid, Magnesium Stearate, Calcium Stearate, Ascorbyl Palmitate, Fractionated Vegetable Oil, Hydrogenated Vegetable Oil, Castor Oil, etc. (See Lubricants in “NAME DECEPTION”). Lubricants enable manufacturing machines to run more efficiently but inhibit eventual

Editorial

dissolution of the nutrient. Each nutrient particle is coated with a layer of Stearic, Palmitic or other fatty acid, which may prevent absorption by a patient with a compromised digestive system. It also presents the problem that delivery of the active ingredient may be considerably further down the intestinal tract than the site originally intended. Potentially this may result in a nutrient being delivered distal to its optimal absorption site. Not only can this impede absorption, in some cases it might be harmful. Consider this with a simple substance such as niacin, which in Time-Release form can cause elevated liver enzymes. In tablet or capsule form, use of Stearic or Palmitic Acid in manufacturing a niacin supplement effectively results in a Time-Release dosage, which may cause the same liver problem or inhibited absorption.

* (In some cases, large tablets [slugs] are made, and then ground up and put in capsules so more density and a higher dosage weight can be achieved.)

Typical multiple vitamin/mineral with additional ingredients

Supplement Facts

Serving Size: One Tablet

One Tablet Contains:	%DV	
Vitamin A (50% as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbyl palmitate)	15 mg	25%
Thiamine (as Thiamine mononitrate)	12 mg	800%
Niacin (as niacinamide)	60 mg	300%
Copper (as cupric oxide)	1 mg	50%
Potassium (as potassium chloride)	10 mg	<1%
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Boron (as aspartate)	200 mcg	*
Tyrosine (as L-Tyrosine)	100 mg	*
Taurine	100 mg	*
Licorice (root) Glycyrrhiza glabra	50 mg	*
Milk Thistle extract (seed) Silybum Marianum (80% Silymarin)	50 mg	*

* Daily Value (DV) not established

Other Ingredients: Sucrose, Cellulose, Lactose monohydrate, Dibasic Calcium Phosphate, Hydroxypropyl Cellulose, Ethylcellulose, Castor oil, Glucose, Carmel color, Gelatin, Silicon Dioxide, Sodium Lauryl Sulfate, FD&C Yellow #5 Lake (Tartrazine), Propylene Glycol, Titanium Dioxide.

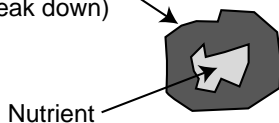
Name Deception

In many cases, an ingredient carries a negative connotation, so the manufacturer uses instead an euphemistically derived alternative.

Deceptive names for Coatings:

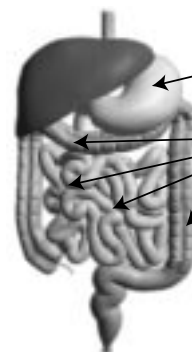
Pharmaceutical Glaze, Confectioners Glaze or Natural Glaze are names for SHELLAC. Natural Vegetable Coating, Natural Protein Coating, Vegetable Coating, and Maize Protein are names for Zein which is CORN PROTEIN.

Layer of Stearic Acid / Ascorbyl Palmitate (digestive system must break down)



Deceptive names for Lubricants:

Stearates are primarily Stearic Acid, alone or complexed with another ingredient, such as magnesium. The National Formulary monograph requires that Stearic Acid be composed of at least 40-percent Palmitic Acid, which has the same properties as refined Stearic Acid. A small amount of Ascorbyl Palmitate (palmitic acid) is added to many products as a "Vitamin



Editorial

C source;” however, its purpose in almost all cases is to act as a lubricant to aid in tableting or capsuling although it has the same negative properties as Stearic Acid (reduced dissolution and inhibited absorption). Castor Oil as an ingredient is usually Hydrogenated Castor Oil; it can exhibit the same properties as Stearic Acid, as can other oils utilized in the manufacture of tablets and most encapsulated products.

What’s not disclosed: INGREDIENTS NOT “ADDED” BY THE MANUFACTURER

Kudos to the FDA for requiring better and more consistent labeling, although the mandated

Product A – Pure ingredients

Supplement Facts		
Serving Size: Eight Capsules		
Eight Capsules Contain:		%DV
Pure Ascorbic Acid	Vitamin C	60 mg 100%
Pure Vitamin D	Vitamin D	400 IU 100%
Pure natural D-alphaTocopheryl	Vitamin E	30 IU 100%
Pure Vitamin K Oil	Vitamin K	80 mcg 100%
Pure Riboflavin	Riboflavin	1.7 mg 100%
Pure Vitamin B12 as Cyanocobalamin	Vitamin B12	6 mcg 100%
Pure Biotin	Biotin	300 mcg 100%
Pure, undiluted Pepsin	Pepsin	300 mg *
Pure, undiluted Pancreatin	Pancreatin	1000 mg *
Pure, undiluted Bromelain	Bromelain	18 mg *
Pure, undiluted Papain	Papain	18 mg *

* Daily Value (DV) not established

Other Ingredients: Gelatin.



Product B – Typical ingredients

Supplement Facts		
Serving Size: Eight Capsules		
Eight Capsules Contain:		%DV
90% Ascorbic Acid, with 10% Corn Starch and Lactose	Vitamin C	60 mg 100%
0.1% Vitamin D dilution in a base of Dicalcium Phosphate, Lactose, Acacia, BHT, Sodium Benzoate, and Sorbic Acid	Vitamin D	400 IU 100%
50% DL-alpha Tocopherol dilution in a base of hydrolyzed protein, Sorbic Acid, and Sodium Benzoate	Vitamin E	30 IU 100%
1% Vitamin K dilution in a base of Dextrose, Acacia and Lactose	Vitamin K	80 mcg 100%
33% Riboflavin, with Mono- and Diglycerides of Fatty Acids surrounding each particle for better flow and flavor masking	Riboflavin	1.7 mg 100%
Cyanocobalamin (0.1% B-12 dilution in a base of Corn Starch with Sodium Benzoate and Sorbic Acid)	Vitamin B12	6 mcg 100%
1% Biotin diluted on a base of Dicalcium Phosphate, Lactose, Sodium Benzoate, and Sorbic Acid	Biotin	300 mcg 100%
Pepsin, standardized with Lactose	Pepsin	300 mg *
Pancreatin, standardized with Lactose	Pancreatin	1000 mg *
Bromelain, standardized with Lactose	Bromelain	18 mg *
Papain, standardized with Lactose	Papain	18 mg *

* Daily Value (DV) not established

Other Ingredients: Gelatin.

Editorial

“Supplement Facts” panel is rather cosmetically flawed. The problem remains, however, and will always remain, that there are ingredients the purchaser of a dietary supplement may never be aware of. These are the ingredients already in the raw material purchased by the manufacturer.

As an example, two apparently identical labels are shown, both of which include what appears to be similar ingredients. Product A is made by a manufacturer with concern for quality ingredients – Product B is made in a very typical manner, with no excipients listed; however, the raw material choices show the difference.

The comparison of Product A and Product B is not unique to dietary supplements – the same issue exists with regard to the labeling of food products. The critical point, however, is that many of the ingredients in raw materials are considered minor manufacturing additives that are not required to be listed on the label. For the FDA to require otherwise – mandating the labeling of each and every “minor ingredient” in a dietary supplement – would create a labeling nightmare. For example, if a manufacturer usually purchased an ingredient in a base of Dicalcium Phosphate, and his supplier ran out, and the only similar ingredient available was in a base of Calcium Carbonate, a label change would be necessary to include this new “sub-ingredient.” But such is not now the case.

The “Supplement Facts” label will bring more information to consumers of dietary supplements, and will do so in a consistent and easily recognizable format. However, disclosure of the “Supplement Facts” is not disclosure of “All The Facts.” Thus, disclosure of many of the ingredients in dietary supplements – Binders, Lubricants, Coatings, Colorings, and Fillers – will remain at the discretion of the manufacturer, in whose interest disclosure may be uncertain.

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Publisher

References

1. U.S.P. 23/ NF 18 *J Pharm Sci* 1986 Jun;75 (6):534-45
2. *Pharmaceutical Technology* 1985 Apr;9(4):28-41
3. Remington's *Pharmaceutical Sciences*, 16th Edition.
4. *The Merck Index*, 12th Edition
5. *Food Chemicals Codex*, 4th Edition
6. Various manufacturers' literature, data and technical directives.

Correction

Methylcobalamin Monograph (*Altern Med Rev* 1998;3(6):461-462).

The Clinical Indications section on Bell's Palsy reads “Evidence suggests methylcobalamin dramatically increased the recovery time for facial nerve function in Bell's palsy.” It should read “Evidence suggests methylcobalamin dramatically ***improved the recovery time for facial nerve function in Bell's palsy.*** ***Also, the section on Male Impotence should read Male Infertility..*** ***We apologize for the errors.***