

STATEMENTS OF FACT ...

- ... can be made on labels as long as they do not make a nutrient content claim or health claim or other claim that requires specific FDA authorization
- ... are covered by free speech rights
- ... must not characterize the nutrient level by using terms that are defined or implied nutrient content claims (free, zero, no, low, high, good source, only, packed with, etc.)
- ... are allowed on conventional foods and dietary supplements as long as they are truthful and not misleading
- ... may be used to describe an amount of a nutrient or a functional component present in a product which allows manufacturers to inform consumers about the level a nutrient or functional component present when a Daily Value has not been established
- ... taken from the Nutrition Facts panel and repeated elsewhere on the label require the following when total fat, cholesterol, saturated fat, or sodium threshold levels are exceeded:
SEE NUTRITION PANEL FOR <NAME OF NUTRIENT> CONTENT



EXAMPLES AND EXPLANATIONS:

ALLOWED: 0g trans fat per serving (the numeral 0 is not a defined nutrient content claim)

NOT ALLOWED: zero trans fat/trans fat free/no trans fat (the terms zero, free, and no are defined nutrient content claims; there are no allowable defined nutrient content claims for trans fat at this time)

ALLOWED: 200mg isoflavones per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: excellent source of isoflavones (the term “excellent source” is a synonym for the nutrient content claim “high” which means 20% or more Daily Value per serving; since FDA has not established a Daily Value for isoflavones, this is an unauthorized nutrient content claim)

ALLOWED: 3g carb per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 3g carb per serving (the term “only” implies a low level of nutrient and low carbohydrate claims are not allowed)

ALLOWED: 100 Calorie Pack (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 100 Calories (the term “only” implies a low level of a nutrient and the definition for low calorie is 40 calories or less per serving; this statement requires the addition of a disclaimer “Only 100 calories, not a low calorie food.”)

ALLOWED: Contains 10mg lutein (factual statement with English use of the word “contains” preceding a quantitative amount)

NOT ALLOWED: Contains lutein (use of the word “contains” without the quantitative amount is a nutrient content claim that means 10% or more Daily Value per serving; since FDA has not established a Daily Value for lutein, this is an unauthorized nutrient content claim)

ALLOWED: Made with oat bran (factual as long as the product contains a significant amount of oat bran in the formulation, generally more than 2% by weight)

NOT ALLOWED: High in oat bran (implies a high level of fiber, which means 20% or more Daily Value per serving; if the product contains less than 20% Daily Value then the claim is not valid)

ALLOWED: Glycemic index of this product is 41 (when based on a clinical trial of the product)

NOT ALLOWED: Low glycemic foods help control diabetes (this is an unauthorized health claim)