



STRUCTURE - FUNCTION CLAIMS

AN OVERVIEW



Claims for Conventional Foods and Dietary Supplements

Among the claims that can be used on food and dietary supplement labels are three categories of claims that are defined by statute and/or FDA regulations:

1. Health claims,
2. Nutrient content claims, and
3. Structure/function claims.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements and procedures for structure/function claims

- **Role of a nutrient or dietary ingredient** intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones."
- **Means by which a nutrient or dietary ingredient acts** to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity."
- **General well-being claims** describe general well-being from consumption of a nutrient or dietary ingredient.
(only if they also say how widespread such a disease is in the United States).

No Pre-Approval, only notification with the text of the claim to FDA within 30 days.

Mandatory Disclaimer:

- FDA has not evaluated the claim.
- Dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

Structure/function claims for conventional foods focus on effects derived from nutritive value, while structure/function claims for dietary supplements may focus on non-nutritive as well as nutritive effects.

FDA is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements.

Process:

- FDA does *not* require conventional food manufacturers to notify FDA about their structure/function claims,
- and disclaimers are not required for claims on conventional foods.

Types of Health Claims:

The so-called '**Function Health Claims**'(or Article 13 claims)

- Relating to the growth, development and functions of the body
- Referring to psychological and behavioural functions
- On slimming or weight-control

The so-called '**Risk Reduction Claims**' (or Article 14(1)(a) claims) on reducing a risk factor in the development of a disease.

Health '**Claims referring to children's development**' (Article 14(1)(b) claims).

Article 13 claims can be made provided:

- based on generally accepted scientific evidence; and
- well understood by the average consumer

(i) **“Health claims”** means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include nutrition claims which describe the physiological role of the nutrient in growth, development and normal functions of the body, other functional claims concerning specific beneficial effect of the consumption of food or its constituents, in the context of the total diet, on normal functions or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or disease, risk reduction claim relating to the consumption of a food or food constituents, in the context of the total diet, to the reduced risk of developing a disease or health related condition;

(ii) **“Nutrition claim”** means any representation which states, suggests or implies that a food has particular nutritional properties which are not limited to the energy value but include protein, fat carbohydrates, vitamins and minerals;

Summary:

- No Specific provisions for claims
- No classification of claims into nutrient function claim/ structure claims.

- Claim approval process, procedure for redressal of non-compliance, advertisement correction to be defined.
- Separate Guidelines for operations of claims approval and complaints redressal to be available.
- Inclusion of list of approved Nutrition claims, Health claims and claims regarding use of words like natural, fresh, pure, original, traditional, premium, real etc. in the guidelines.
- Introduction of additional claim for Low Glycemic Index (GI) foods in the Nutrition claims table.
- “Claim” means any representation which is printed, oral, audio or visual and states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise;

Nutrient Function Claim is that which describes the physiological role of the nutrient in growth, development and normal functions of the body.

Example:

- nutrient 'A' (naming a physiological role of nutrient A in the body in maintenance of health and promotion of normal growth & development). Food X is a rich source of / high in nutrient 'A'.

Other Function Claim - that describe the specific beneficial effects of the consumption of food(s) or their constituents, in the context of the total diet or normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Example:

- “Substance A (naming the effect of substance A on improving or modifying physiological function or biological activity, associated with health). Food Y contains X grams of substance A.”

Possible example of positive list:

Nutrient/Food: Calcium or Calcium and Vitamin D and osteoporosis

Conditions for claim:

- The food is a source or high in calcium or in calcium and vitamin D and
- A statement that the beneficial effect is obtained with a daily recommended intake (RDA)

Claim Statement:

- Adequate Calcium (or Calcium and Vitamin D) intake throughout life, in a balanced diet are essential for bone health and to reduce the risk of osteoporosis

Food: Dietary saturated fat and cholesterol and risk of coronary heart disease (CHD)

Conditions:

- Low saturated fat and cholesterol per serving
- A statement that the beneficial effect is obtained with a diet low in fat, saturated fat and cholesterol and physical activity

CLAIM STATEMENT:

- While many factors affect heart disease, diets low in fat, saturated fat and cholesterol may reduce the risk of heart disease

Consider:

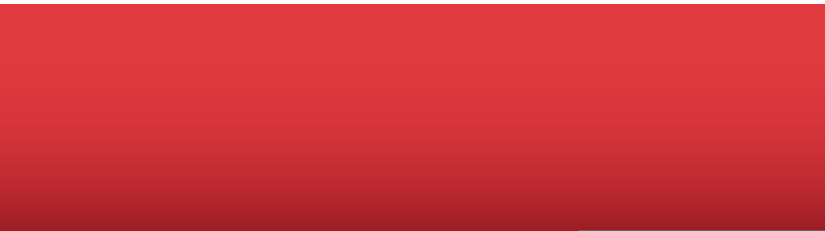
- Costs and national scientific and regulatory capabilities
 - Culture
 - Prescriptive or flexible
 - Enforcement options and implications
 - Consumer safety

Remember the Goal:

- Protect consumers
- Better and more informed food/diet choices
- Respect fair competition and trade
- Promote and protect innovation

CODEX ?

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Claims



DuPont Nutrition & Health combines in-depth knowledge of food and nutrition with current research and expert science to deliver unmatched value to the food, beverage and dietary supplement industries.

We are innovative solvers, drawing on deep consumer insights and a broad product portfolio to help our customers turn challenges into high-value business opportunities

