INFORMATION NOTE

Recent Developments in the Regulation of Health Food in the United States

1. Background

1.1 The Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004, at its meeting on 23 November 2004, requested the Research and Library Services Division to provide updated information regarding the series of research reports on health food regulation issued in 2001. This information note provides the Bills Committee with information on the recent developments in the regulation of health food in the United States.

2. Codex Alimentarius Commission[1]

2.1 Internationally, the regulation of health claims on food is in a developmental state and varies widely among countries and areas. Regulation of health claims is complicated by the fact that there are various types of health claims.[2] Among the countries and areas reviewed by the Codex Alimentarius Commission, most of them have no regulations specific to health claims carried by food labels including those of health food, followed closely by countries and areas that disallow any reference to diseases in a claim. A number of countries and areas permit specified "disease risk-reduction", "nutrient function" or "other function" claims, and the United States (US) is an example of such cases.[3]

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1 Codex Alimentarius Commission is an international organization created in 1963 by the World Health Organization and the Food and Agriculture Organization of the United Nations to develop food standards, guidelines and related texts such as codes of practice, as well as promoting co-ordination of food standards work undertaken by international governmental and non-governmental organizations.

2 Hawkes (2004).

3 Ibid.

3. Highlights of the regulatory framework for dietary supplements

Claims for dietary supplements

3.1 Claims that can be used on dietary supplement labels fall into three categories, namely health claim, nutrient content claim and structure/function claim. Disease claims that purport to cure, treat, prevent, mitigate or diagnose specific diseases are not allowed to be used on dietary supplement labels.

3.2 Both health claims and nutrient content claims require approval from the Food and Drug Administration (FDA). A health claim can be used in a label if it passes a review of scientific evidence. In the case of "qualified health claim", it must include qualifying language as part of the claim to indicate that the evidence supporting the claim is limited. For nutrient content claim, it can be used in a label if the claim is made in accordance with FDA's authorizing regulations.

3.3 For structure/function claims, no pre-approval or authorization is required by FDA. Manufacturers must submit a notification including the text of the claim to FDA no later than 30 days after marketing dietary supplement products. They must ensure that the claims are truthful and not misleading. A disclaimer is needed for use of such claims.

Product safety

3.4 Manufacturers of dietary supplements are responsible for ensuring that their products are safe before they are marketed. There is no provision in the law for FDA to "approve" dietary supplements for safety or effectiveness before they are marketed. Once a dietary supplement is marketed, the burden of proof falls on FDA to prove that the product is "unsafe" before it can be removed from the marketplace.

3.5 The manufacturer or distributor must notify FDA if he or she intends to market a dietary supplement that contains a New Dietary Ingredient. The manufacturer or distributor must demonstrate why the ingredient is reasonably expected to be safe for use in a dietary supplement.

Regulation of advertisements

3.6 Advertisement of dietary supplements is regulated by the Federal Trade Commission, FDA, as well as the US Postal Inspection Service. In general, the law prohibits "unfair or deceptive acts or practices" and any false advertisement which is "misleading in a material respect".

4. Definitions

Health food

4.1 There is no legal definition of the term "health food" in the US. Products for oral consumption are regulated by FDA as either drug or food.

Drug

4.2 The Federal Food, Drug, and Cosmetic Act (Act) defines the term "drug" as:[4]

(a) articles recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(d) articles intended for use as a component of any article specified above.

4.3 Please refer to Appendix I for the full definition of drug.

Food

4.4 Under the Act, the term "food" is defined as:[5]

(a) articles used for food or drink for man or other animals;

(b) chewing gum; and

(c) articles used for components of any such article.

[4] Section 201(g)(1) of the Act.
[5] Section 201(f) of the Act.

Dietary Supplement

4.5 Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), a dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids or powders. They can also be in other forms, such as bars, but if they are, information on their labels must not represent the products as conventional food or a sole item of a meal or diet. Whatever their forms may be, DSHEA places dietary supplements in a special category under the general umbrella of "food", and requires that every such product be labelled as a dietary supplement.[6]

4.6 For a full definition of dietary supplement, please refer to Appendix II.

5. Claims for dietary supplements

5.1 Claims that can be used on dietary supplement labels fall into three categories, namely health claim, nutrient content claim and structure/function claim. Disease claims that purport to cure, treat, prevent, mitigate or diagnose specific diseases are not allowed to be used on dietary supplement labels. (For criteria determining if a statement is a disease claim, please refer to Appendix III.) The responsibility for ensuring the validity of these claims rests with the manufacturer and FDA.

Health claim

5.2 A health claim by definition has two essential components:

(a) a substance (whether a food, food component, or dietary ingredient); and

(b) a disease or health–related condition.

[6] United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2001).

Authorization of claims

5.3 A statement lacking either one of these two components does not meet the regulatory definition of a health claim. There are two ways by which FDA determines which health claims may be used on a label or in labelling for dietary supplements:

(a) the Nutrition Labeling and Education Act of 1990 (NLEA) provides for FDA to issue regulations authorizing health claims for food and dietary supplements after a careful review of the scientific evidence submitted in health claim petitions.[7] For a list of approved health claims for use on food labels, including dietary supplement labels, please refer to Appendix IV.

When FDA decides whether to authorize a health claim, it evaluates, among other considerations, whether the evidence supporting the relationship that is the subject of the claim meets the *significant scientific agreement standard*.[8] NLEA also permits any interested person to petition FDA to issue a regulation regarding a health claim; and

(b) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for "qualified health claims" where the quality and strength of the scientific evidence fall below those required for FDA to issue an authorizing regulation.

In making a qualified health claim, qualifying language must be included as part of the claim to indicate that the evidence supporting the claim is limited. Please refer to Table 1 for qualifying language for qualified health claims. FDA either conducts its own review or hires an appropriate third party to conduct a scientific review. In reaching its determination, FDA evaluates the review report, the totality of the publicly available evidence, public comments submitted within the comment period, as well as considering how the proposed qualified claim will affect consumers' dietary choices.

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7 Title 21 of the Code of Federal Regulations section 101.14.

8 This standard derives from section 403(r)(3)(B)(i) of the Act, which provides that FDA shall authorize a health claim to be used on conventional food and dietary supplements if the agency *"determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."*

For qualified health claims, FDA will notify the petitioner within 270 days upon receipt of the petition of its determination.[9] If a petitioner or other party disagrees with the FDA determination, that party may request reconsideration. FDA would reconsider its determination if the party presents significant new relevant evidence, or provides a persuasive analysis that FDA's interpretation of the original evidence was incorrect.

Table 1 – Qualifying Language for Qualified Health Claims

Scientific Ranking	Appropriate Qualifying Language
First level: This level meets the *significant scientific agreement standard* and reflects a *high level of comfort* among qualified scientists that the claimed substance/disease relationship is scientifically valid.	Not Applicable.
Second level: This level represents a *moderate/good level of comfort* among qualified scientists that the claimed substance/disease relationship is scientifically valid. Qualified scientists would rank the relationship as "promising", but not definitive.	... "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third level: This level represents a *low level of comfort* among qualified scientists that the claimed substance/disease relationship is scientifically valid. It would have low consistency with statements from authoritative bodies or be ranked as low in terms of scientific support by qualified scientists.	"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."
Fourth level: This level represents an *extremely low level of comfort* among qualified scientists that the claimed substance/disease relationship is scientifically valid. It would have very low consistency with conclusions of authoritative bodies or be ranked very low in terms of scientific support by qualified scientists.	"Very limited and preliminary scientific research suggests ... FDA concludes that there is little scientific evidence supporting this claim."

Sources:
(1) United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003b).
(2) United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003c).

[9] United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003c).

Nutrient content claim

5.4 NLEA permits the use of label claims that characterize the level of a nutrient in a food made in accordance with FDA's authorizing regulations. A nutrient content claim describes the level of a nutrient or dietary substance in a product, using terms such as *free*, *high*, and *low*, or compares the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. Percentage claims for dietary supplements are another category of nutrient content claims. An example is "40% omega-3 fatty acids, 10 mg per capsule".

Structure/function claim

5.5 A structure/function claim describes the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones". In addition, it may characterize the 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", or it may describe general well-being from consumption of a nutrient or dietary ingredient. A structure/function claim may also describe a benefit related to a nutrient-deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the US.

Notification of claims

5.6 Manufacturers of dietary supplements that make structure/function claims on labels or in labelling must submit a notification including the texts of the structure/function claims to FDA no later than 30 days after marketing the dietary supplement products. FDA does not pre-approve or authorize such claims. Manufacturers must ensure that the claims are truthful and not misleading.

Disclaimer

5.7 Manufacturers of dietary supplements are responsible for ensuring the accuracy and truthfulness of structure/function claims. If a dietary supplement label includes a structure/function claim, under title 21 of the Code of Federal Regulations section 101.93, a disclaimer shall be adopted as follows:

Text for disclaimer

5.8 The disclaimer shall state:

"This statement has (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."

Placement

5.9 The disclaimer shall be placed adjacent to the statement with no intervening material, or linked to the end of the statement with a symbol (e.g. an asterisk) which is also placed adjacent to the disclaimer.

Typesize

5.10 The disclaimer shall appear in bold-face type in letters of a typesize no smaller than one-sixteenth inch.

6. Product safety

6.1 Under DSHEA, manufacturers of dietary supplements are responsible for ensuring that their products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there is no provision in the law for FDA to "approve" dietary supplements for safety or effectiveness before they reach consumers. In addition, unlike drug products, manufacturers and distributors of dietary supplements are not required by law to record, investigate or forward to FDA any reports they receive of injuries or illnesses that may be related to the use of their products. Under DSHEA, once a dietary supplement product is marketed, FDA has the responsibility to prove that the product is "unsafe", before it can take action to restrict the product's use or order its removal from the marketplace.

Pre-market notification

6.2 DSHEA requires that a manufacturer or distributor notifies FDA if he or she intends to market a dietary supplement in the US that contains a New Dietary Ingredient (NDI)[10]. The manufacturer or distributor must demonstrate to FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement, unless it has been recognized as a food substance and is present in the food supply. The notification is to be provided at least 75 days before the product is introduced or delivered for introduction into interstate commerce.

[10] An NDI is a dietary ingredient that was not marketed in the US before 15 October 1994.

6.3 Apart from notification, any person may file with the Secretary of Health and Human Services a petition proposing the issuance of an order prescribing the conditions under which an NDI under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed. The decision of the Secretary shall be final.

6.4 There is no legal provision that requires a firm to disclose to FDA or consumers the information it has about the safety or purported benefits of the dietary supplement products. It is up to each firm to set its own policy on disclosure of such information.

7. Regulation of advertisements

7.1 The Federal Trade Commission (FTC) collaborates with FDA in regulating advertising, including infomercials, for dietary supplements sold to consumers. Advertising and promotional materials delivered by mail are subject to regulation by a different federal department, the US Postal Inspection Service. FTC evaluates claims made in the advertisements of dietary supplements under the Federal Trade Commission Act which prohibits "unfair or deceptive acts or practices" and any false advertisement which is "misleading in a material respect".[11]

8. Enforcement

8.1 In the 10 years since DSHEA was passed in 1994, the dietary supplement industry has grown from roughly US$8 billion (HK$62.1 billion)[12] in annual sales to an estimated US$16 billion (HK$124.2 billion) to US$19 billion (HK$147.5 billion).[13] Given the size of the market, critics claim that Congress has not provided FDA with enough enforcement funds as regards dietary supplements. Since 2002, the first year FDA received money specifically earmarked for DSHEA enforcement, Congress has appropriated US$500,000 (HK$3.88 million) annually for the enforcement of DSHEA.[14] The Executive Director of the National Nutritional Foods Association[15] stated in a congressional testimony in October 2003 that FDA had "never fully implemented or adequately enforced" the DSHEA requirements.

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11 For details of the regulation of advertisements, please refer to paragraphs 15.1 to 15.4 of the research report on "Regulation of Health Food in the United States" issued in 2001.

12 The average exchange rate of US dollar to Hong Kong dollar in 2003 was US$1=HK$7.763.

13 Triplett (2004).

14 Ibid.

15 The National Nutritional Foods Association is an organization which represents the interests of manufacturers and retailers of a wide variety of natural products.

8.2 FDA admits that it has limited resources to analyze the composition of food products, including dietary supplements. Therefore, enforcement priorities go to products believed to be unsafe, fraudulent, or in violation of the law. The agency does not analyze dietary supplements before they are sold to consumers. The manufacturer is responsible for ensuring that the "Supplement Facts" label and ingredient list are accurate, that the dietary ingredients are safe, and that the content matches the amount declared on the label.

8.3 Critics note that because prescription and over-the-counter drugs are subject to stricter rules, they can be removed from the marketplace faster than dietary supplements. For example, FDA removed the diet drug fen-phen within three months of learning that it was suspected to be involved in 33 cases of rare heart valvular diseases. Yet it took 155 deaths over 10 years before FDA was able to get the supplement ephedra off the market.[16, 17] That is because FDA, rather than the manufacturer, must prove the existence of safety risks for dietary supplements before it can remove the supplements from the market.

8.4 On the advertising front, according to the Director of FTC's Bureau of Consumer Protection, since DSHEA was passed in 1994, FTC has filed or settled more than 100 law enforcement actions challenging allegedly false or misleading claims by dietary supplement advertisers. Most recently, FTC and FDA have formed a joint task force to pursue similar claims.

9. Recent development

9.1 In November 2004, FDA announced a strategy outlining steps the agency planned to take to continue implementing and enforcing DSHEA. The objectives of the strategy are to improve the transparency, predictability and consistency of FDA's scientific evaluations and regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false or misleading claims. The strategy focuses on three areas:

(a) monitoring and evaluating product and ingredient safety;

(b) ensuring product quality; and

(c) monitoring and evaluating product labelling.

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16 Triplett (2004).

17 In February 2004, FDA published a final rule concluding that dietary supplements containing ephedrine alkaloids (ephedra) presented an unreasonable risk to the public health and were adulterated. The sale of ephedra is now prohibited in the US.

Monitoring and evaluating product and ingredient safety

9.2 FDA announced that it would work collaboratively with federal and other partners to develop the evidentiary base FDA used to make safety and enforcement decisions about dietary ingredients and dietary supplements. Upon detection of a signal which identifies a possible safety concern[18], FDA can seek input from an independent third-party review. In addition, FDA is taking steps to ensure that dietary supplements containing NDI are not adulterated.

Ensuring product quality

9.3 On 13 March 2003, FDA published a proposed rule on current good manufacturing practice (GMP) requirements for dietary supplements in the Federal Register (FR).[19] The proposed rule is intended to help prevent super-potent and sub-potent products, wrong ingredients in dietary supplements, presence of contaminants (e.g. bacteria, pesticide, glass and lead), under-filled containers, foreign materials in a dietary supplement container, improper packaging and mis-labelling. FDA is currently reviewing and evaluating comments on the proposed rule and plans to publish GMP final rule by early 2005.

Monitoring and evaluating product labelling

9.4 Dietary supplements that bear unsubstantiated structure/function claims in their labelling can defraud and harm consumers. As such, FDA is taking the following actions to help ensure that dietary supplement labelling is truthful and non-misleading:

(a) continuing to identify and take action against dietary supplements making claims that are not supported by scientific evidence;

(b) developing and publishing a draft guidance[20] addressing what constitutes adequate scientific substantiation for structure/function claims and claims of a benefit related to a nutrient-deficiency disease[21];

[18] Such signals can come from federal, state and local counterparts, adverse event reports, foreign regulatory actions, media reports, information from consumer groups and consultation with experts.

[19] 68 FR 12158.

[20] 69 FR 64962.

[21] At present, the Act does not define what constitutes "substantiation" for a claim made for dietary supplements.

(c) identifying and taking enforcement action against products whose labelling fails to reveal material facts, targeting those products that pose the greatest risks to consumers;

(d) obtaining and analyzing samples of dietary supplements in the marketplace to verify that the contents are consistent with the labelling; and

(e) reviewing "Supplement Facts" panels on dietary supplement labels to determine whether the substances listed as dietary ingredients can be lawfully marketed in dietary supplements.

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Appendix I

Definition of Drug

A.I.1 Under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (Act), the term "drug" is defined as

(a) articles recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(d) articles intended for use as a component of any article specified in clause (a), (b), or (c). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of the Act or sections 403(r)(1)(B) and 403(r)(5)(D) of the Act, is made in accordance with the requirements of section 403(r) of the Act is not a drug solely because the label or the labelling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of the Act is not a drug under clause (c) solely because the label or the labelling contains such a statement.

Appendix II

Definition of Dietary Supplement

A.II.1 Under section 201(ff) of the Federal Food, Drug, and Cosmetic Act (Act), the term "dietary supplement":

(a) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(i) a vitamin;

(ii) a mineral;

(iii) an herb or other botanical;

(iv) an amino acid;

(v) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(vi) a concentrate, metabolite, constituent, extract, or combination of the above;

(b) means a product that:

(i) is intended for ingestion in tablet, capsule, powder, soft gel, gel cap, or liquid form;

(ii) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(iii) is labelled as a dietary supplement; and

(c) does:

(i) include an article that is approved as a new drug under section 505 of the Act or licensed as a biologic under section 351 of the Public Health Service Act (42 United States Code 262) and was, prior to such approval, certification or license, marketed as a dietary supplement or as a food unless the Secretary of Health and Human Services has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labelling for such dietary supplement, is unlawful under section 402(f) of the Act; and

Appendix II (cont'd)

(ii) not include:

- an article that is approved as a new drug under section 505 of the Act, certified as an antibiotic under section 507 of the Act, or licensed as a biologic under section 351 of the Public Health Service Act (42 United States Code 262); or

- an article authorized for investigation as a new drug, antibiotic or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the Act.

Appendix III

Criteria for Determining If a Statement is a Disease Claim

A.III.1 Under title 21 of the Code of Federal Regulations (C.F.R.) section 101.93(g), the Food and Drug Administration will find that a statement about a product claims to diagnose, mitigate, treat, cure or prevent disease if it claims, explicitly or implicitly, that the product:

(a) has an effect on a specific disease or class of diseases;

(b) has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(c) has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(d) has an effect on a disease or diseases through one or more of the following factors:

(i) the name of the product;

(ii) a statement about the formulation of the product;

(iii) citation of a publication or reference;

(iv) use of the term "disease" or "diseased"; or

(v) use of pictures, vignettes, symbols, or other means;

(e) belongs to a class of products that is intended to diagnose, mitigate, treat, cure or prevent a disease;

(f) is a substitute for a product that is a therapy for a disease;

(g) augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure or prevent a disease or class of diseases;

(h) has a role in the body’s response to a disease or to a vector of disease;

(i) treats, prevents or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(j) otherwise suggests an effect on a disease or diseases.

Appendix IV

Approved Health Claims for Use on Food Labels, including Dietary Supplement Labels

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Calcium and osteoporosis (21 C.F.R. 101.72)	• High in calcium; • Assimilable (Bio-available); • Supplements must disintegrate and dissolve; and • Phosphorus content cannot exceed calcium content.	• Indicating the disease depends on many factors by listing risk factors or the disease, e.g. gender, race, or age; • Primary target population: females, Caucasian and Asian races, and teens and young adults in their bone-forming years; • Additional factors necessary to reduce risk: eating healthful meals and regular exercise; • Mechanism relating calcium to osteoporosis: optimizes peak bone mass; and • Food or supplements containing more than 400 mg calcium must state that total intakes of greater than 2 000 mg calcium provide no added benefit to bone health.	• Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Sodium and hypertension (21 C.F.R. 101.74)	• Low sodium.	• Requiring terms: ◆ "Sodium"; and ◆ "High blood pressure"; and • Including a physician statement if the claim defines high or normal blood pressure (e.g. "individuals with high blood pressure should consult their physicians").	• Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary fat and cancer (21 C.F.R. 101.73)	• Low fat (fish and game meats: "extra lean").	• Requiring terms: ◆ "Total fat" or "fat"; and ◆ "Some types of cancers" or "some cancers"; and • Forbidding specifying types of fats or fatty acids that may be related to the risk of cancer.	• Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Dietary saturated fat and cholesterol and risk of coronary heart disease (21 C.F.R. 101.75)	• Low saturated fat; • Low cholesterol; and • Low fat (fish and game meats: "extra lean").	• Requiring terms: ◆ "Saturated fat and cholesterol"; and ◆ "Coronary heart disease" or "heart disease"; and • Including a physician statement if the claim defines high or normal blood total (and low-density lipoprotein (LDL)) cholesterol (e.g. "individuals with elevated blood total (or LDL) cholesterol should consult their physicians").	• While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Fiber-containing grain products, fruits, and vegetables and cancer (21 C.F.R. 101.76)	• A grain product, fruit, or vegetable that contains dietary fiber; • Low fat; and • Good source of dietary fiber (without fortification).	• Requiring terms: ◆ "Fiber", "dietary fiber", or "total dietary fiber"; and ◆ "Some types of cancer" or "some cancers"; and • Forbidding specifying types of dietary fiber that may be related to the risk of cancer.	• Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (21 C.F.R. 101.77)	• A fruit, vegetable, or grain product that contains fiber; • Low saturated fat; • Low cholesterol; • Low fat; • At least 0.6 grams of soluble fiber per Reference Amount (RA) (without fortification); and • Soluble fiber content provided on label.	• Requiring terms: ◆ "Fiber", "dietary fiber", "some types of dietary fiber", "some dietary fibers", or "some fibers"; ◆ "Saturated fat" and "cholesterol"; and ◆ "Heart disease" or "coronary heart disease"; and • Including a physician statement if the claim defines high or normal blood total (and LDL) cholesterol (e.g. "individuals with elevated blood total (or LDL) cholesterol should consult their physicians").	• Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Fruits and vegetables and cancer (21 C.F.R. 101.78)	• A fruit or vegetable; • Low fat; and • Good source (without fortification) of at least one of the followings: ◆ vitamin A; ◆ vitamin C; or ◆ dietary fiber.	• Requiring terms: ◆ "Fiber", "dietary fiber", or "total dietary fiber"; ◆ "Total fat" or "fat"; and ◆ "Some types of cancer" or "some cancers"; • Characterizing fruits and vegetables as "foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber"; • Characterizing specific food as a "good source" of one or more of the followings: dietary fiber, vitamin A, or vitamin C; and • Forbidding specifying types of fats or fatty acids or types of dietary fiber that may be related to the risk of cancer.	• Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. [*Name of food*] is high in vitamin A and C, and it is a good source of dietary fiber.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Folate and neural tube defects (21 C.F.R. 101.79)	• "Good source" of folate (at least 40 mcg folate per serving); • Dietary supplements, or food in conventional food form that are naturally good sources of folate (i.e. only non-fortified food in conventional food form); • The claim shall not be made on products that contain more than 100% of the Reference Daily Intake for vitamin A as retinol or preformed vitamin A or vitamin D; • Dietary supplements shall meet the United States Pharmacopoeia standards for disintegration and dissolution or otherwise bio-available; and • Amount of folate required.	• Requiring terms: ◆ Terms that specify the relationship (e.g. women who are capable of becoming pregnant and who consume adequate amounts of folate), "folate", "folic acid", "folacin", "folate, a B vitamin", "folic acid, a B vitamin," "folacin, a B vitamin," "neural tube defects", "birth defects, spinal bifida, or anencephaly", "birth defects of the brain or spinal cord - anencephaly or spinal bifida", or "spinal bifida or anencephaly, birth defects of the brain or spinal cord"; and • Including information on the multi-factorial nature of neural tube defects, and the safe upper limit of daily intake.	• Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Dietary sugar alcohol and dental caries (21 C.F.R. 101.80)	• Sugar free; • The sugar alcohol must be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of the above; and • When a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7.	• Requiring terms: ◆ "Does not promote", "may reduce the risk of", "useful [or is useful] in not promoting", or "expressly [or is expressly] for not promoting" dental caries; ◆ "Sugar alcohol", "sugar alcohols", or the name or names of the sugar alcohols, e.g. sorbitol; and ◆ "Dental caries" or "tooth decay"; • Including a statement stating that "frequent between-meal consumption of foods high in sugars and starches can promote tooth decay"; and • Packages with less than 15 square inches of surface area available for labelling may use a shortened claim.	• Full claim: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [*name of food*] do not promote tooth decay; or • Shortened claim (on small packages only): Does not promote tooth decay.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Soluble fiber from certain food and risk of coronary heart disease (21 C.F.R. 101.81)	• Low saturated fat; • Low cholesterol; • Low fat; • Including either (1) one or more eligible sources of whole oats, containing at least 0.75 g whole oat soluble fiber per RA; or (2) psyllium seed husk containing at least 1.7 g of psyllium husk soluble fiber per RA; and • Amount of soluble fiber per RA declared in nutrition label.	• Requiring terms: ◆ "Heart disease" or "coronary heart disease"; ◆ "Soluble fiber" qualified by either "psyllium seed husk" or the name of the eligible source of whole oat soluble fiber; ◆ "Saturated fat" and "cholesterol"; and ◆ "Daily dietary intake of the soluble fiber source necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to this level of intake". Additional required label statement • Food products bearing a psyllium seed husk health claim must also bear a label statement concerning the need to consume them with adequate amounts of fluids. E.g. "*NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing.*" (21 C.F.R. 101.17(f))	• Soluble fiber from foods such as [*name of soluble fiber source, and, if desired, name of food product*], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food product*] supplies [*x*] grams of the [*necessary daily dietary intake for the benefit*] soluble fiber from [*name of soluble fiber source*] necessary per day to have this effect.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Soy protein and risk of coronary heart disease (21 C.F.R. 101.82)	• At least 6.25 g soy protein per RA; • Low saturated fat; • Low cholesterol; and • Low fat (except that food made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from the "low fat" requirement).	• Requiring terms: ◆ "Heart disease" or "coronary heart disease"; ◆ "Soy protein"; and ◆ "Saturated fat" and "cholesterol"; • Specifying daily dietary intake levels of soy protein associated with reduced risk; and • Specifying amount of soy protein in a serving of food.	• Twenty-five grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of soy protein; or • Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [*name of food*] provides [*x*] grams of soy protein.

Appendix IV (cont'd)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Plant sterol/stanol esters and risk of coronary heart disease (21 C.F.R. 101.83)	• At least 0.65 g plant sterol esters per RA of spreads and salad dressings, or at least 1.7 g plant stanol esters per RA of spreads, salad dressings, snack bars, and dietary supplements; • Low saturated fat; • Low cholesterol; and • Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "see nutrition information for fat content".	• Requiring terms: ◆ "May" or "might" reduce the risk of coronary heart disease; ◆ "Heart disease" or "coronary heart disease"; and ◆ "Plant sterol esters" or "plant stanol esters" ; except "vegetable oil" may replace the term "plant" if vegetable oil is the sole source of the sterol/stanol ester; • Specifying plant stero/stanol esters are part of a diet low in saturated fat and cholesterol; • Not attributing any degree of coronary heart disease risk reduction; • Specifying the daily dietary intake of plant sterol or stanol esters necessary to reduce coronary heart disease risk, and the amount provided per serving; and • Specifying that plant sterol or stanol esters should be consumed with two different meals each day.	• Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of vegetable oil sterol esters; or • Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of plant stanol esters.

Source: United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2000).

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