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Regulation of Health Food in the United States

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C O N T E N T S

EXECUTIVE SUMMARY

1. In the United States, there are products called dietary supplements. The ingredients of dietary supplements may include vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, extracts or concentrates. Dietary supplements are allowed to carry claims of health benefits. They can be found in many forms such as pills, tablets, capsules, powders, etc.

2. The Food and Drug Administration (FDA) is responsible for overseeing the safety, manufacturing and labelling of dietary supplements while the Federal Trade Commission is responsible for regulating the advertising of dietary supplements.

3. The main legislation governing the regulation of dietary supplements is the Dietary Supplement and Health Education Act (DSHEA). DSHEA broadens the definition of dietary supplements and places the responsibility for ensuring their safety on manufacturers. It also specifies labelling requirements, and gives the FDA the authority to promulgate good manufacturing practice (GMP) regulations for dietary supplements. Yet, no GMP regulations for dietary supplements have been promulgated to date.

4. The FDA does not analyze dietary supplements before they are sold to consumers. No review and approval of supplement ingredients and products are required from the FDA before marketing. Manufacturers of dietary supplements are required to notify the FDA within 30 days **after** marketing a dietary supplement product. However, if they wish to market a new dietary ingredient, they have to notify the FDA 75 days **before** marketing.

5. Dietary supplements are allowed to carry three types of claims, nutrient-content claims, health claims and structure / function claims. The FDA defines nutrient-contents claims and promulgates rules as to which substances can use these claims. Health claims must be approved by the FDA before they can be included in the labels of dietary supplements. The law requires that notification of using a nutrient-content claim or health claim be made to the FDA by the company seeking to use that claim 120 days prior to using that claim. Structure / function claims can be used without FDA authorization. When a manufacturer uses a structure / function claim, he is responsible for making sure that the claim is truthful and not misleading. There must also be a disclaimer accompanying the structure / function claim.

6. Dietary supplements are widely available in health food stores, grocery, drug and national discount chain stores, as well as through mail-order catalogues, TV programmes, the internet and direct sales.

REGULATION OF HEALTH FOOD IN THE UNITED STATES

PART 1 - INTRODUCTION

1. Background

1.1 In March 2000, the Panel on Health Services requested the Research and Library Services Division to conduct a research on the regulation of health food in overseas places.

2. Scope of the Research

2.1 The objective of this research is to study the regulation of health food in Australia, Taiwan, the United States and Hong Kong. The scope includes differentiation of health food from conventional food and medicine, the relevant regulation and its enforcement, and the channel through which health food is marketed. This study mainly discusses food products not sold in their conventional forms: they include products sold in the form of capsules, pills, tablets or powder, etc.

2.2 The United States is chosen because there is legislation governing a subset of foods called dietary supplements. Dietary supplements can be in the form of capsules, pills, tablets or powder, etc. and may carry health claims.

2.3 This research report forms part of the series of reports discussing the regulation of health food. There are four separate research reports on this subject.

3. Methodology

3.1 Information for this research report is obtained from the Internet, government reports and relevant reference materials.

3.2 The average exchange rate in 1999 between HK$ and US$ was HK$7.758 = US$1.[1]

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[1] Census and Statistics Department, *Hong Kong Annual Digest of Statistics*, 2000 edition.

PART 2 - REGULATION OF HEALTH FOOD IN THE UNITED STATES

4. Definitions

Health Food

4.1 There is no legal definition of "health food" in the United States (US). Products for oral consumption are regulated by the US Food and Drug Administration (FDA) as either drugs or foods.

Drugs

4.2 The Federal Food, Drug, and Cosmetic Act defines a drug as "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and as "an article (other than food) intended to affect the structure or any function of the body".[2]

4.3 The law also requires that new drugs be shown to be safe and effective for their intended uses before marketing. It is the responsibility of the company seeking to market a drug to test the drug and submit evidence that the drug is safe and effective.

4.4 Drugs are allowed to carry drug claims which are claims to cure, treat, prevent, mitigate or diagnose specific diseases. The use of drug claims has to be authorized by the FDA.

Food

4.5 The Federal Food, Drug, and Cosmetic Act defines the term "food" as follows:

(1) articles used for food or drink for man or other animals,

(2) chewing gum, and

(3) articles used for components of any such article.[3]

[2] Section 201(g)(1)(B) and (g)(1)(C) of the Federal Food, Drug and Cosmetic Act.

[3] Chapter II of the Federal Food, Drug and Cosmetic Act.

4.6 In the US, foods are assumed to be safe, unless there is actual evidence of harm. They must be produced under sanitary conditions and their labelling must be truthful and not misleading. Their labels are allowed to carry health claims provided that they meet certain requirements laid down by the FDA. A health claim is a statement which shows a relationship between a nutrient in a food product and a disease or health related condition. If a manufacturer of a food product wishes to include a health claim in the food label, there needs to be sufficient scientific agreement among qualified experts that the claim is factual and truthful.

4.7 There is also a subset of foods called dietary supplements (detailed in paragraphs below). Both dietary supplements and foods are allowed to carry health claims. Since this research report aims to study food products not sold in their conventional form but in the form of capsules, pills, tablets or powder, etc., therefore, the regulation of health claims carried by foods is not discussed here.

Dietary Supplements

4.8 A dietary supplement is any product taken by mouth, intended to supplement the diet, which contains "dietary ingredients" and its label clearly states that it is a dietary supplement.

4.9 The "dietary ingredients" contained in dietary supplements may include vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, extracts or concentrates. Dietary supplements can be found in many forms such as pills, tablets, capsules, powders, etc. Examples are garlic in tablets and ginkgo biloba in capsules.

4.10 Dietary supplements are not drugs. Drugs must undergo clinical studies to determine their effectiveness, safety, possible interactions with other substances, and appropriate dosages. All these data are required to be reviewed by the FDA and the use of drugs must also be authorized by the FDA before they can be marketed. FDA does not authorize or test dietary supplements.

4.11 Instead, dietary supplements are considered as a subset of foods under the Dietary Supplement Health and Education Act (DSHEA). Yet, they are not represented for use as a conventional food or as a sole item of a meal or the diet. They are normally used by consumers to promote and maintain healthy bodily functions.

Health Claims and Related Claims Carried by Dietary Supplements

4.12 Under DSHEA, manufacturers of dietary supplements are allowed to use three types of claims, namely, nutrient-content claims, health claims or disease claims and nutritional support claims which include "structure / function claims".

Nutrient-Content Claims

4.13 Nutrient-content claims describe the level of a nutrient in a dietary supplement. For example, a dietary supplement containing at least 200 mg of calcium per serving may carry the claim, "high in calcium". Nutrient-content claims are defined by the FDA.

Health Claims or Disease Claims

4.14 Health claims or disease claims show a link between a substance and a disease or a health related condition. An example of these claims is the relationship between an appropriate intake of folic acid during or before pregnancy and a decreased risk of neural tube defect in infants. Manufacturers of dietary supplements are required to obtain an authorization from the FDA before they can apply a health claim on the labels of dietary supplements. To date, the FDA has authorized 11 health claims, four of which can be made about dietary supplements. Please see Appendix I for the list of FDA authorized health claims.

Nutritional Support Claims - Structure / Function Claims

4.15 Nutritional support claims describe a link between a nutrient and a deficiency disease which can result if the nutrient is lacking in the diet. For example, the label of a Vitamin C supplement can state that Vitamin C prevents scurvy. When this type of claims is used, the label must mention the prevalence of the nutrient-deficiency disease in the US.

4.16 Nutritional support claims also refer to the dietary supplement's effect on the body's structure (such as the skeletal system) or function (such as the circulatory system), including its overall effect on maintaining a body's structure or function or a person's general well being. These are known as structure / function claims. Examples of structure / function claims are "promotes regularity", "helps maintain cardiovascular health", or "supports the immune system".

4.17 The FDA does not pre-approve or authorize structure / function claims. Rather, when the manufacturer uses a structure / function claim, he is responsible for making sure that the claim is truthful and not misleading.

Distinction Between Health Claims and Structure/Function Claims

4.18 Since there often is a fine line between health claims and structure/function claims, the FDA in 2000 published a final rule on how to distinguish health claims from structure / function claims. This final rule is summarized as follows[4]:

> "The final rule precludes express disease claims ("prevent osteoporosis") and implied disease claims ("prevents bone fragility in post-menopause women") without prior FDA review. The final rule clarifies that such express and implied disease claims can be made through the name of a product ("Carpaltun", "CircuCure"), through a statement about the formulation of a product (contains aspirin), or through the use of pictures, vignettes, or symbols (electrocardiogram tracings).
>
> The final rule permits claims that do not relate to disease. These include health maintenance claims ("maintains a healthy circulatory system"), other non-disease claims ("for muscle enhancement", "helps you relax"), and claims for common, minor symptoms associated with life stages ("for common symptoms of PMS [post-menopause symptoms]", "for hot flashes")."

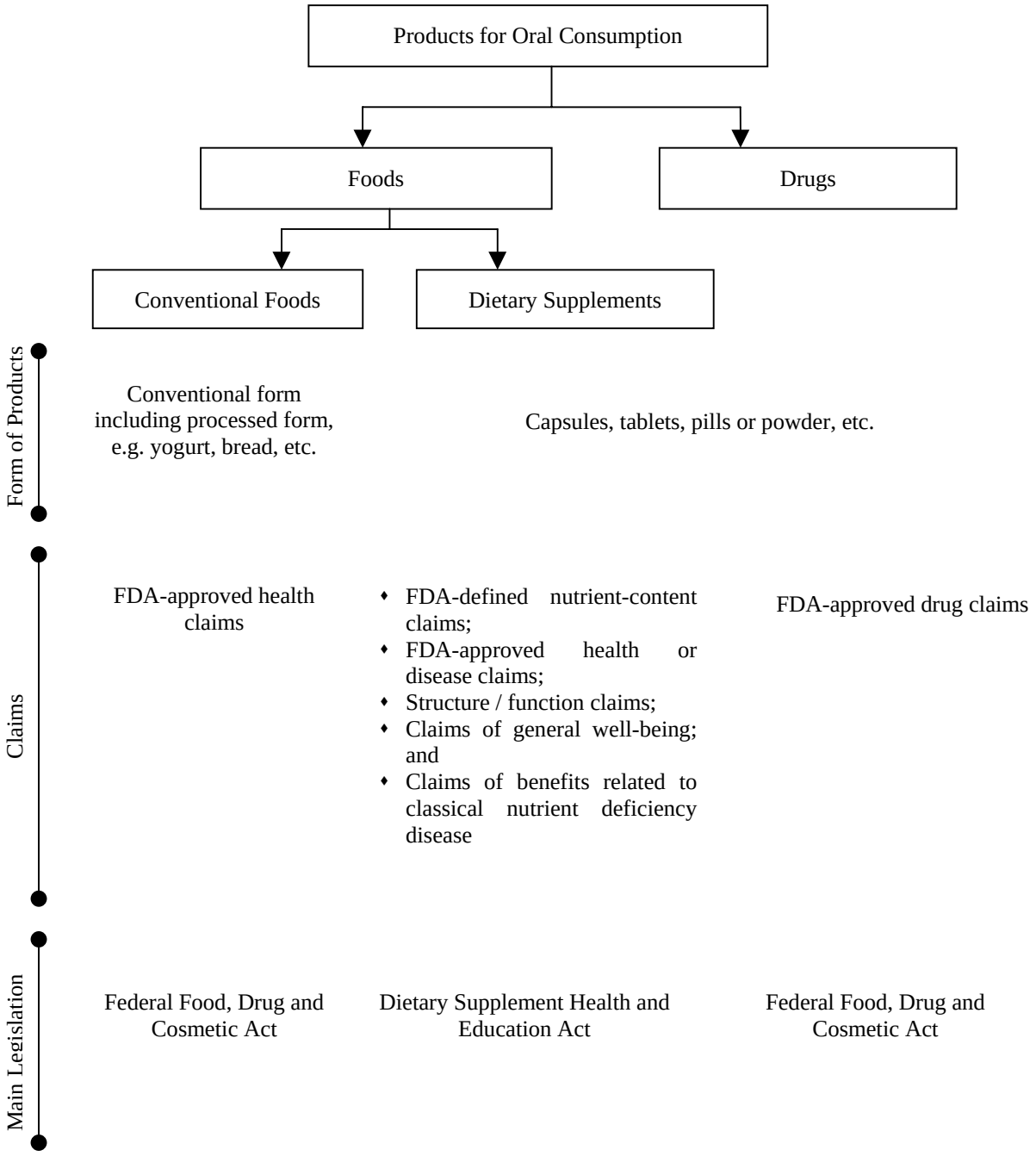
4.19 The final rule also revised the definition of "disease" and expanded the scope of acceptable structure / function claims. For example, manufacturers can now make structure / function claims about *common* conditions associated with ageing, pregnancy, menopause and adolescence. However, *serious* conditions associated with ageing, pregnancy, menopause, and adolescence, such as toxemia of pregnancy, and osteoporosis, will continue to be treated as diseases.

4.20 Appendix II gives some examples of prohibited and allowable structure / function claims.

[4] FDA, *FDA Talk Paper: FDA Finalizes Rules For Claims on Dietary Supplements*, 5 January 2000.

4.21 Diagram 1 summarizes the regulation of products for oral consumption in the US.

Diagram 1 - Regulation of Products for Oral Consumption



PART 3 - COUNTRY BACKGROUND

5. Basic Facts

5.1 In 1998, the US has a population of 270 561 000[5]. As at the third quarter of year 2000, the Gross Domestic Products (GDP) of the US amounted to US$10,039.4 billion (or HK$77,885.7 billion).[6]

5.2 It is noted from the statement made by the Commissioner of FDA before the Committee on Government Reform of the US House of Representatives dated 25 March 1999 that more than half of the US adult population used dietary supplement products.

5.3 In 1997, consumers in the US spent more than US$12 billion (or HK$93 billion) on dietary supplements and sales continue to grow at a 10% annual rate.[7] In 1999, consumer sales of dietary supplement increased to US$14.7 billion (or HK$114 billion)[8]. Per capita spending on dietary supplements was therefore about US$54 (or HK$419).

5.4 According to the congressional estimates[9] made at the time DSHEA was enacted in 1994, there were about 600 dietary supplement manufacturers in the US producing approximately 4 000 products. There is no readily available information on the quantity of imported dietary supplements since they are not differentiated from other food imports in trade statistics.

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5 US Census Bureau, *Frequently Requested Population Tables* at http://www.census.gov/statab/www/pop.html.

6 Bureau of Economic Analysis of US Department of Commerce, *National Income and Product Accounts* at http://www.bea.doc.gov/bea/dn/gdplev.htm.

7 http://www.ndmainfo.org/chpa/10_2.html

8 US General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"*, July 2000 at http://www.gao.gov/.

9 Commission on Dietary Supplement Labels, *Report of the Commission on Dietary Supplement Labels*, November 1997 at http://www.health.gov/dietsupp/

PART 4 - REGULATORY FRAMEWORK OF DIETARY SUPPLEMENTS

6. Legislation

6.1 The main piece of legislation relating to the regulation of dietary supplements is the Dietary Supplement Health and Education Act 1994 (DSHEA) (detailed in paragraph 6.2 below). Other relevant Federal laws include: (1) the Federal Food, Drug and Cosmetic Act which governs the regulation of foods including dietary supplements as dietary supplements are considered as a subset of foods; (2) the Federal Trade Commission Act which provides the Federal Trade Commission with the authority to regulate advertisements for all consumer products, including dietary supplements; (3) the Nutrition Labelling and Education Act (NLEA) which deals with health claims made about dietary supplements; and (4) the Food and Drug Adminstration Modernization Act of 1997 which provides provisions to expedite the process of approving new health claims made about dietary supplements.

Dietary Supplement Health and Education Act 1994, DSHEA

6.2 DSHEA was passed in 1994. It set up a new framework for the regulation of dietary supplements. Before the passage of DSHEA, the principal statute regulating dietary supplements was the Federal Food, Drug, and Cosmetic Act. Under the Federal Food, Drug, and Cosmetic Act, any product which claimed to prevent, treat or mitigate a disease, or to affect the structure or any function of the body would be regulated as a drug by the FDA. Otherwise, it would be regulated as a food. DSHEA *amended* the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements[10].

6.3 In 1994, DSHEA was enacted with the intent to meet the concerns of consumers and manufacturers of dietary supplements that safe and appropriately labelled products should remain available to those who want to use them. The US Congress considered that there might be a positive relationship between sound dietary practice and good health and there might be a connection between dietary supplement use, reduced healthcare expenses and disease prevention. DSHEA was therefore passed with an intent to give manufacturers more freedom to market dietary supplement products and to provide information about their products' benefits in product labelling.

[10] Since the aim of DSHEA was not to repeal the Federal Food, Drug and Cosmetic Act, therefore, areas relating to the regulation of dietary supplements not governed by DSHEA were still subject to the Federal Food, Drug and Cosmetic Act. Examples are prohibited acts and penalties of the infringement of the regulation of dietary supplements.

6.4 DSHEA broadens the definition of dietary supplements and places the responsibility for ensuring their safety on manufacturers. It also specifies labelling requirements, and provides the FDA with the authority to establish good manufacturing practice (GMP) regulations for dietary supplements.

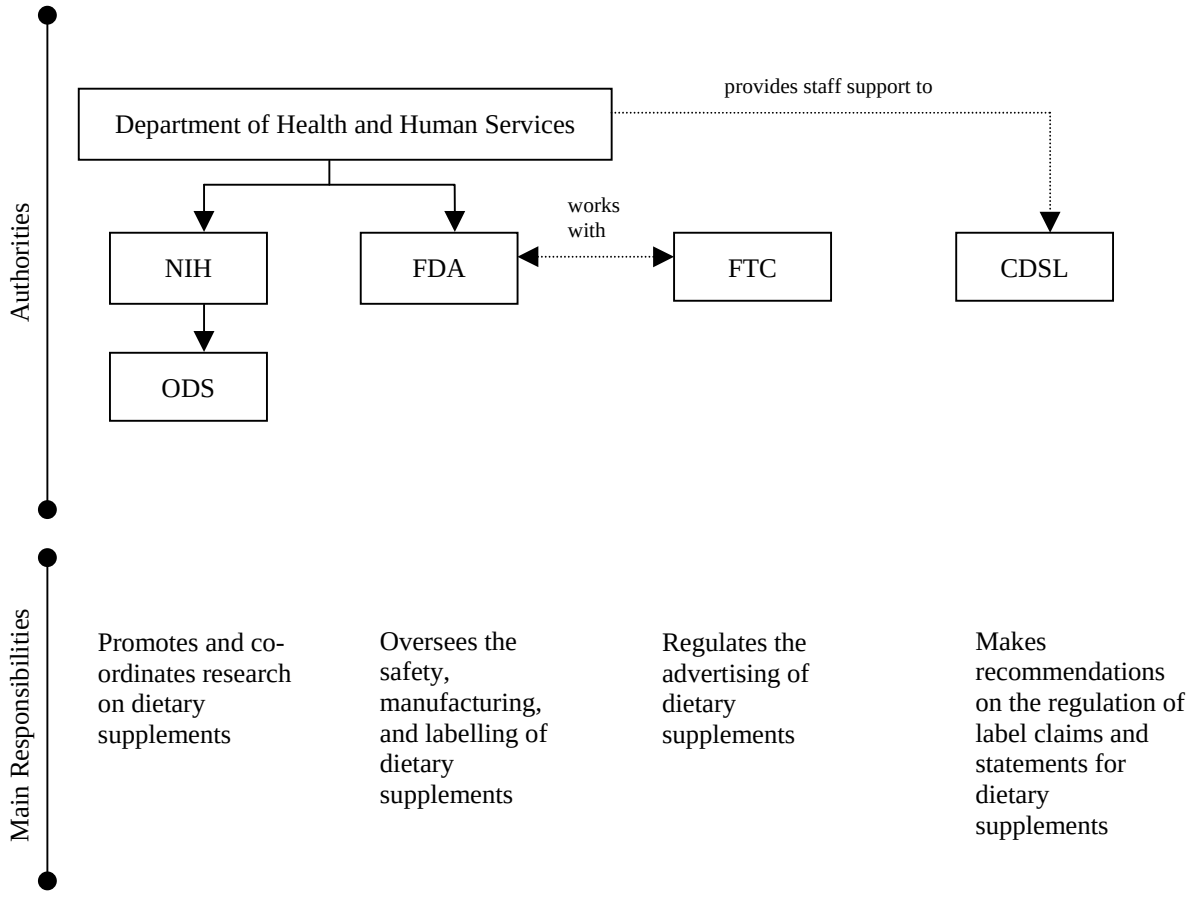
6.5 DSHEA also creates the Office of Dietary Supplements within the National Institutes of Health and the Commission on Dietary Supplement Labels. These authorities are detailed in the following section.

7. Authorities Involved in the Regulation of Dietary Supplements

Introduction

7.1 The FDA is the principal agency responsible for regulating dietary supplements. Other authorities involved in the regulation include the Federal Trade Commission (FTC), the Office of Dietary Supplements (ODS) and the Commission on Dietary Supplement Labels (CDSL). Diagram 2 shows the relationship of the authorities involved in the regulation of dietary supplements and their main responsibilities.

Diagram 2 - Authorities Involved in the Regulation of Dietary Supplements



CDSL - Commission on Dietary Supplements Labels
FDA - Food and Drug Administration
FTC - Federal Trade Commission
NIH - National Institute of Health
ODS - Office of Dietary Supplements

Food and Drug Administration

7.2 The FDA is an agency within the Department of Health and Human Services and is responsible for administering DSHEA.

7.3 The FDA is responsible for overseeing the safety, manufacturing and labelling of dietary supplements. It has authority to take action against any dietary supplement product which is found to be unsafe or which makes unsubstantiated claims or unapproved drug claims. In addition, it has authority to remove any dietary supplement which presents a significant or unreasonable risk of injury or illness to people.

Federal Trade Commission

7.4 The FTC regulates the advertising of dietary supplements while the FDA has primary responsibility for regulating the labelling of dietary supplements. Owing to their shared jurisdiction, both the FTC and the FDA work together to ensure that their enforcement efforts are consistent. The FTC also takes actions against any products which make unsubstantiated claims in advertisements of dietary supplements.

7.5 The FTC is headed by five Commissioners, nominated by the US President and confirmed by the US Senate, each serving a seven-year term. The US President chooses one Commissioner to act as Chairman of the FTC. No more than three Commissioners can be of the same political party.

Office of Dietary Supplements

7.6 The ODS is a Congressionally mandated office established within the National Institutes of Health (NIH)[11]. Its mandates are listed as follows[12]:

(1) Explore the role of dietary supplements to improve health care;
(2) Promote scientific study of dietary supplements in maintaining health and preventing chronic disease;
(3) Conduct and co-ordinate research on dietary supplements at NIH;
(4) Collect and compile databases of federally funded research and scientific papers on dietary supplements;
(5) Co-ordinate funding for research on dietary supplements at NIH; and
(6) Provide advice to other agencies of the Department of Health and Human Services related to dietary supplements.

[11] The National Institutes of Health (NIH) is one of the eight health agencies of the Public Health Service in the US and is also part of the US Department of Health and Human Services. It is the focal point for medical research in the US.

[12] Office of Dietary Supplements, *About ODS*, at http://ods.od.nih.gov/about/mandate.html.

7.7 The ODS does not have any regulatory function related to dietary supplements. It co-ordinates, sponsors or organizes workshops to promote scientific study of and research on dietary supplements.

Commission on Dietary Supplement Labels

7.8 The CDSL is an independent panel of experts mandated by DSHEA to study and make recommendations to the US President and US Congress on the regulation of label claims and statements for dietary supplements, including procedures for the evaluation of such claims. The Secretary of Health and Human Services is also required by DSHEA to promulgate rules on the recommendations proposed by the CDSL within two years after the recommendations were made.

7.9 The Commission has seven members who are all presidential appointees with expertise or experience in the manufacture, regulation, distribution, and use of dietary supplements. DSHEA also stipulates that three of the members should be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and that one of those three is to have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences.

PART 5 - CONTROL OF DIETARY SUPPLEMENTS

8. Introduction

8.1 Before the passage of DSHEA, a dietary supplement for which a health related claim was made was regulated either as a drug, which had to be shown to be safe and effective before marketing, or as a food, for which prior authorization to make a health claim was required if the claim concerned a disease or health related condition. If the claim concerned a non-disease related effect on the structure or function of the body and the claimed effect was derived from a food attribute, such as nutritive value, the claim was considered a food claim, and prior authorization was not required.

8.2 After the passage of DSHEA, manufacturers are given more freedom to market dietary supplements and to provide information about their products' benefits in product labelling.

9. Safety of Dietary Supplements

9.1 The FDA does not analyze dietary supplement products before they are sold. The manufacturer is responsible for ensuring that the ingredient list is accurate, and that both the ingredients contained in the dietary supplements and the supplement products are safe. He is also required to make sure that the content matches the amount declared on the label.

9.2 Under DSHEA, once a dietary supplement is marketed, the FDA has the responsibility for showing that a dietary supplement is unsafe before it can take action to restrict the product's use. If safety problems arise after marketing, DSHEA allows the Secretary of Health and Human Services to ban a dietary supplement if it is found to be an "imminent hazard"[13].

10. Good Manufacturing Practice

10.1 Dietary supplements have always been regulated as foods and therefore, have been and still are subject to Good Manufacturing Practice (GMP) regulations applicable to foods. GMP would ensure that dietary supplements are made under conditions which would result in safe and properly labelled products.

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[13] *Statement* made by the Commissioner of Food and Drug Administration before the Committee on Government Reforms of the US House of Representatives dated 25 March 1999.

10.2 DSHEA gives the FDA authority to establish special GMP for dietary supplements. The FDA published a draft GMP for dietary supplements in February 1997. The final version of GMP for dietary supplements is currently under review. Until separate dietary supplement GMP regulations are established, dietary supplements are subject to food GMP regulations.

11. Pre-Market Assessment / Notification

11.1 DSHEA states that manufacturers of dietary supplements have the responsibility for checking the safety of dietary supplements and determining the truthfulness of label claims. No review nor approval of supplement ingredients and products is required from the FDA before marketing.

11.2 However, dietary supplement manufacturers who wish to market a new ingredient (that is, an ingredient not marketed in the US before 1994) have to **notify** the FDA before marketing. They have two options. The first involves submitting to the FDA information which supports their conclusion that a new ingredient can "reasonably be expected to be safe". That submission has to be made at least 75 days before the product is expected to go on the market. "Safe" means that the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the product's labelling. The information the manufacturer submits becomes publicly available 90 days after the FDA receives it.

11.3 Another option for manufacturers is to petition the FDA, asking the FDA to establish the conditions under which the new dietary ingredient would "reasonably be expected to be safe". To date, the FDA has received no such petitions.

11.4 According to a report submitted by the US General Accounting Office (GAO)[14] to the US Congressional Committees entitled 'Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods[15] [16], the GAO found that potentially unsafe products may reach consumers as there was a lack of a clearly defined safety standard for new dietary ingredients in dietary supplements. The FDA has not defined in regulations nor provided guidance on the evidence needed to document the safety of new dietary ingredients in the 75-day pre-market notification. In the absence of such guidance, manufacturers of dietary supplements will have to make their own best estimate of how much evidence is adequate to ensure safety. While some manufacturers may thoroughly evaluate and document the safety of new dietary ingredients, other may not. This may allow some potentially unsafe products to reach the marketplace.

12. Post-Market Vigilance

12.1 The FDA's post marketing responsibilities include monitoring safety through voluntary dietary supplement adverse event reporting, and checking product information, such as labelling, claims, package inserts, and accompanying literature of dietary supplements.

12.2 The FDA says in its website that it has limited resources to analyze the composition of dietary supplements and priority is placed on public health emergencies and products which may have caused injury or illness. Since the FDA considers dietary supplements as relatively low risk products, how frequent the monitoring of dietary supplements products would be conducted depends on what is allowed by its resources.

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[14] The US General Accounting Office (GAO), commonly called the investigative arm of Congress or the congressional watchdog, is an agency working for the US Congress. The US Congress asks GAO to study the programmes and expenditures of the federal government. GAO is an independent and nonpartisan organization. It advises the US Congress and the heads of executive agencies about ways to make government more effective and responsive.

[15] Functional foods are a subset of foods which provide the basic attributes of traditional foods, i.e. taste, aroma, or nutritive value and claim to provide an additional health benefit. It is in the form of conventional food such as butter-like spreads or cereals but **not** in the form of pills, capsules, tablet or powder.

[16] US General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"*, July 2000 at http://www.gao.gov/.

13. Regulation of Claims

Nutrient-Content Claims

13.1 Nutrient-content claims are defined by the FDA and there are specific rules as to which substances can be listed using these nutrient content claims.

Health Claims

13.2 The Nutrition Labelling and Education Act (NLEA) authorizes the FDA to allow dietary supplement labels to carry statements which describe the relationship between supplement ingredients and disease or health-related conditions. Such statements are known as "health claims" and may appear on the labels of dietary supplements qualified to bear such claims.

13.3 When the FDA decides whether to authorize a health claim, it evaluates, among other considerations, whether the evidence supporting the relationship meets the **significant scientific agreement**[17] standard. The FDA will authorize a health claim to be used on dietary supplements if the FDA "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 agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."[18]

13.4 Any person may petition the FDA to issue a regulation regarding a health claim. When the FDA authorizes a health claim, any person can use it on any product which meets the nutritional criteria. The use of this health claim is not restricted to the person who submitted the petition to the FDA.

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[17] Significant scientific agreement means that the validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined. The assessment of significant scientific agreement derives from the conclusion that there is a sufficient body of sound, relevant scientific evidence which shows consistency across different studies and among different researchers and permits the key determination of whether a change in the dietary intake of the substance will result in a change in a disease endpoint. Source: Office of Special Nutritionals in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, 22 December, 1999.

[18] Office of Special Nutritionals in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, 22 December, 1999.

Pearson v Shalala

13.5 The US Court of Appeal for the District of Columbia Circuit, in a court case named Pearson v Shalala[19] in 1999, directed the FDA to revise the existing regulation of health claims carried by dietary supplements. In that case, the plaintiffs challenged FDA's health claim regulations for dietary supplements. The FDA had refused to approve four health claims proposed by the plaintiffs because the FDA found that the scientific evidence supporting the four claims was inconclusive and therefore did not satisfy the significant scientific agreement standard. The court, however, ruled in favour of the plaintiffs and held unconstitutional under the First Amendment the four FDA rules which suppressed the four health claims proposed by the plaintiffs. It was also held in that case that the FDA might prohibit only health claims which were "inherently misleading" (i.e. false) and the FDA must approve claims (even potentially misleading claims) which had been accompanied by reasonable disclaimers (i.e. the disclaimers would eliminate the potential deception and avoid consumer misinterpretation).

13.6 According to the Opening Remarks made by the Director of Center for Food Safety and Nutrition of the FDA at the Public Meeting on Implementing the Pearson Court Decision and Other Health Claim Issues held on 4 April 2000, four elements in the court decision were identified, each of which had significant impact on the regulation of dietary supplements.

13.7 First, the FDA was instructed to reconsider whether to authorize the four claims at issue. To date, two of these health claims have been authorized. Secondly, in the absence of significant scientific agreement, the FDA must determine if the scientific evidence in support of the claims would outweigh the scientific evidence against the claim. Thirdly, the FDA must consider whether the disclaimer or other qualifying language could make the health claim non-misleading to consumers. Finally, the FDA was also instructed to clarify the significant scientific agreement standard for authorizing health claims.

13.8 The significance of this case is that the FDA may not suppress health claims on the basis that they do not satisfy the significant scientific agreement standard so long as the addition of a disclaimer can render the claims non-misleading.

Structure / Function Claims

13.9 Manufacturers of dietary supplements can use structure / function claims without FDA authorization. They base their claims on their review and interpretation of the scientific literature. Like all label claims, structure / function claims must be true and not misleading.

[19] 164 F.3d 650 (D.C. Cir. 1999).

13.10 Structure / function claims are easy to spot because, on the label, they must be accompanied with the disclaimer "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

13.11 Manufacturers who plan to use a structure / function claim on a particular product must **inform** the FDA of the use of the claim no later than 30 days after the product is first marketed. While the manufacturers must be able to substantiate the claim, they do not have to share the substantiation with the FDA or make it publicly available.

13.12 DSHEA requires the manufacturer of a dietary supplement making a statement of nutritional support (including statements of structure / function claims) to have substantiation that such statement is truthful and not misleading. DSHEA, however, does not specify what constitutes adequate substantiation. The Commission on Dietary Supplement Labels issues guidance on what quantity and quality of evidence should be used to substantiate the statement.

13.13 Listed below are the documents suggested by the Commission on Dietary Supplements Labels to be required for substantiation:

(1) A notification letter;

(2) Identification of the product's ingredients,

(3) Evidence to substantiate the statement,

(4) Evidence to substantiate safety,

(5) Assurances that good manufacturing practice were followed; and

(6) The qualifications of the person who reviewed the data on safety and efficacy.

13.14 If the submitted claims promote the products as drugs instead of supplements, the FDA can advise the manufacturer to change or delete the claim or the products have to be approved as a drug under the Federal Food, Drug and Cosmetic Act.

14. Control of Labelling

14.1 The label of a dietary supplement must contain enough information about the composition of the product so that consumers can make informed choices. (The information must be presented in FDA-specified format.) The manufacturer must make sure the label information is truthful and not misleading.

14.2 Information which is required on the labels of dietary supplements includes[20]:

(1) Statement of identity (e.g. ginseng);

(2) Net quantity of contents (e.g. 60 capsules);

(3) The following statement (for structure / function claims only),

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.";

(4) Directions for use (e.g. take one capsule daily);

(5) Supplement Facts panel (lists serving size, amount, and active ingredient);

(6) Other ingredients in descending order of predominance and by common name or proprietary blend;

(7) Name and place of business of manufacturer, packer or distributor. This is the address to write to for more product information.

14.3 One weakness in the control of labelling pointed out by GAO was that the FDA did not provide any guidance or prescribe any regulation as to when or which safety-related information should be included on the dietary supplements' labels, such as information on the maximum safe dosage of the ingredients in the product, possible interactions between the ingredients and drugs, etc. For example, a herb called St John's Wort may decrease the efficacy of a drug used to treat HIV infection, but consumers may not be able to determine this from the dietary supplement label. This might endanger the health of some consumers.

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[20] FDA, *An FDA Guide to Dietary Supplements*, January 1999 at http://www.fda.gov/fdac/features/1998/598_guid.html.

15. Regulation of Advertisements

15.1 The FTC regulates dietary supplement advertising. It evaluates claims in advertising of dietary supplements under the Federal Trade Commission Act which prohibits "unfair or deceptive acts or practices" and any false advertisements which is "misleading in a material respect". The FTC issued an industry guide entitled "Dietary Supplements: An Advertising Guide for Industry" in 1998. The advertising principles laid down in the above guide is that "all parties have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims. … In evaluating the adequacy of support for a claim, the Federal Trade Commission consults with experts in a wide variety of fields, including those with a background in botanicals and traditional medicines."[21]

15.2 The FTC may begin an investigation in different ways: letters from consumers or businesses, Congressional inquiries, or articles on consumer or economic subjects.[22]

15.3 If the FTC believes a violation of the law has occurred, it may attempt to obtain voluntary compliance by entering into a consent order with the company. A company which signs a consent order need not admit that it violated the law, but it must agree to stop the disputed practices.

15.4 If a consent agreement cannot be reached, the FTC may issue an administrative complaint. If an administrative complaint is issued, a formal proceeding which is similar to a court trial begins before an administrative law judge[23]. If a law violation is found, a cease and desist order or other appropriate relief may be issued. Initial decisions by administrative law judges may be appealed to the full FTC. Final decisions issued by the FTC may be appealed to the US Court of Appeals and, ultimately, to the US Supreme Court.

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21 Federal Trade Commission, *Business Guide for Dietary Supplement Industry Released by FTC Staff*, 18 November 1998 at http://www.ftc.gov/opa/1998/9811/dietary.htm.

22 Federal Trade Commission, *How the FTC Brings an Action*, at http://www.ftc.gov/ftc/action.htm.

23 An administrative law judge is responsible for conducting formal proceedings, interpreting the law, applying FTC regulations, and carrying out policies of the FTC in the course of administrative adjudications. Although he is an employee of the FTC, he has to carry out his duties and responsibilities independently. To insure independent exercise of these functions, his appointment is absolute. The judge is not subject to FTC's efficiency ratings, promotions, or demotions; compensation is established by the Office of Personnel Management independent of the FTC's recommendations. The FTC can take disciplinary action against the judge only when good cause is established before the Merit Systems Protection Board, an independent quasi-judicial agency in the executive branch of the US government, after opportunity for hearing.

16. Imported Dietary Supplements

16.1 All imported dietary supplements are required to meet the same standard as domestic dietary supplements, i.e. they must be pure, wholesome, safe to consume and produced under sanitary conditions and they must contain informative and truthful labelling in English.

16.2 To ensure that the FDA is notified of all dietary supplements imported into the US, the importer must file an entry notice and an entry bond with the US Customs Service pending a decision regarding the admissibility of the dietary supplement products. The FDA is notified by the US Customs Service of the entry and makes a decision as to the products' admissibility. If the FDA does not wish to examine the products, the products are allowed to enter the US market.

16.3 If the FDA decides to examine the products, a FDA representative will collect a sample from the shipment for laboratory evaluation. Decision to collect a sample is made based on (1) nature of the product, (2) FDA priorities, and (3) past history of the products[24]. If the analysis indicates that the products are in compliance, the shipment may be permitted to enter the US market. If there is a violation, the products will be refused admission.

16.4 If the products are refused admission, the importer is required to either re-export or destroy the products under the US Customs Service. If the refused products are not destroyed or re-exported, the US Customs Service will issue to the importer a Notice for Redelivery. Failure to redeliver the refused products may result in the US Customs Service assessing liquidated damages against the importer's bond.

16.5 There is no readily available information about the frequency of examination of imported dietary supplements taken by the FDA.

17. Problems Reporting

17.1 There is no mandatory requirement for industry, consumers or healthcare professionals to report adverse events resulting from consumption of dietary supplements.

[24] FDA, *FDA Import Procedures*, at http://vm.cfsan.fda.gov/~lrd/import.html.

17.2 The FDA currently collects reports of adverse events associated with the use of dietary supplements through its MedWatch system, which accepts voluntary reports of adverse events from health professionals and consumers for serious adverse events related to FDA-regulated products. The FDA also receives reports of adverse events associated with the use of dietary supplements through the CFSAN Adverse Event Monitoring system. All reports FDA receives concerning adverse events associated with dietary supplements are entered into CFSAN's Special Nutritionals Adverse Event Monitoring System (SN/AEMS) database for evaluation and monitoring.

17.3 However, the FDA does not investigate every adverse report received. Therefore, there is no certainty that the reported adverse reports can be attributed to a particular product or ingredient as the information contained in the SN/AEMS database is voluntarily submitted and may not be complete. The GAO noted and the FDA officials recognized this weakness but the FDA officials said that a lack of resources had precluded them from taking actions to correct it[25].

17.4 According to the SN/AEMS Web Report as last updated in October 1998, there were a total of 2 621 adverse events reported, involving 3 451 products. These products include dietary supplements, infant formulas, and medical foods. Of the 2 621 adverse events reports, there were 15 reports which included the term, dietary supplement.

18. Infringement of Regulations

18.1 The Federal Food, Drug and Cosmetic Act provides that any food, including a dietary supplement, is "adulterated" if it "may be injurious to health". The FDA may take any action against any dietary supplement which is adulterated. DSHEA adds new safety provisions to the above provisions specifying that a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury when used according to label directions." Any infringement of the above legislation may result in fines, imprisonment or both.

18.2 The FDA reacts to safety issues through means such as applying direct pressure on the manufacturers to voluntarily cease marketing of an ingredient or a product, requesting a product recall or using public announcements to alert consumers to safety concerns.

[25] US General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"*, July 2000 at http://www.gao.gov/.

18.3 It was noted from the speech made by the Chairman of the Committee on Government Reform of the US House of Representatives that the number of deaths of consumers caused by the adulteration of dietary supplements was small: "as for the safety of dietary supplements, 16 deaths had been reported in 1998. Compared with 106 000 people who die a year from prescription drugs and 42 000 a year from automobile accidents in the US, dietary supplements could be considered as low risk products."[26]

19. Recent Development in the Regulation of Dietary Supplement

19.1 In January 2000, the FDA announced a ten-year plan to achieve effective regulation of dietary supplements under DSHEA. The goal of the plan is to have a science-based programme which fully implements DSHEA by the year 2010. For details of the plan, please see Appendix III.

[26] Burton, Dan, *"Opening Statement"* made at the meeting of Committee on Government Reform of the US House of Representatives about "*Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?*", 25 March 1999.

PART 6 - SALE AND DISTRIBUTION OF DIETARY SUPPLEMENTS

20. Sale: Application Procedures

Step 1: Pre-Market Notification for a Nutrient-Content Claim or Health Claim

20.1 Prior to the enactment of the Food and Drug Administration Modernization Act of 1997 (FDAMA), manufacturers and importers of dietary supplements could not use a health claim or nutrient-content claim unless the FDA published a regulation authorizing such a claim. After the enactment in 1997, manufacturers and importers were permitted to use claims based on current, published, authoritative statements[27] issued by certain federal scientific bodies[28]. The aim of the FDAMA is to expedite the process by which the scientific basis for such claims is established[29].

20.2 Under the FDAMA, manufacturers and importers are required to submit a notification to the FDA 120 days prior to using the claim. The notification must identify the statement and provide the specific wording of the claim. During the 120-day time period, the FDA is expected to review the notification and, if appropriate, the FDA can prohibit or modify the claim. Otherwise, in the absence of FDA action, the claim is authorized under the FDAMA.

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27 The Food and Drug Administration Modernization Act of 1997 states that an authoritative statement: (1) is "about the relationship between a nutrient and a disease or health-related condition for a health claim", or "identifies the nutrient level to which the claim refers" for a nutrient content claim, (2) is "published by the scientific body", (3) is "currently in effect", (4) "shall not include a statement of an employee of the scientific body made in the individual capacity of the employee", (5) reflects a consensus within the identified scientific body if published by a subdivision of one of the federal scientific bodies, and (6) shall be based on a deliberative review by the scientific body of the scientific evidence. Source: FDA, *Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body*, 11 June 1998.

28 The FDA considers the following federal scientific bodies as sources of authoritative statements: the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Surgeon General within the Department of Health and Human Services, the Food and Nutrition Service, the Food Safety and Inspection Service and the Agricultural Research Service within the Department of Agriculture. Although the National Academy of Sciences is not a federal agency, the FDAMA specifically identifies it as a scientific body for the purposes of FDAMA. Source: FDA, *Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body*, 11 June 1998.

29 The FDAMA still upholds the "significant scientific agreement" standard for health claims (detailed in paragraph 13.3). The FDA would determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement.

Step 2: Pre-Market Notification for a New Dietary Ingredient

20.3 Since the US Congress considered dietary ingredients marketed prior to the passage of DSHEA to be generally safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like conventional foods. If a dietary supplement contains a new dietary ingredient (i.e. first marketed after 15 October 1994), manufacturers are required to notify the FDA at least 75 days before marketing and to include in the notification the basis for its conclusion that the dietary supplement will "reasonably be expected to be safe". There is no requirement that the manufacturer wait for a safety determination from the FDA before marketing the product. The FDA reviews the notification and the file will be placed on public display 90 days following its receipt.

Step 3: Notification of Marketing a Dietary Supplement

20.4 DSHEA requires that manufacturers and importers of dietary supplements bearing statements of structure / function claims or claims of general well-being from consumption of a nutrient or dietary supplement, or claims of benefits related to classical nutrient deficiency diseases notify the FDA within 30 days ***after*** marketing. These claims must be substantiated by evidence and must be accompanied by the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.".

21. Distribution: Distribution Channels

21.1 Though commonly associated with health food stores, dietary supplements are also sold in grocery, drug and national discount chain stores, as well as through mail-order catalogues, TV programmes, the internet, and direct sales.

22. Notifications Sent to FDA

22.1 According to the CFSAN 2000 Program Priorities Report Card[30], CFSAN received 24 notifications for new dietary ingredients between January and September, 2000. All were reviewed within the statutory timeframes. Of these 24 notifications, nine were filed without comment (i.e., the FDA did not object at the time of the review to its marketing); 15 were objected to either because they had inadequate information to provide a basis to conclude that it would reasonably be expected to be safe or because they failed to meet procedural requirements.

[30] CFSAN of the FDA, *CFSAN 2000 Program Priorities Report Card*, 5 December 2000, at http://vm.cfsan.fda.gov/~dms/cfsand00.html#part-ii.

22.2 During the period January 2000 through October 2000, the FDA received approximately 1 400 structure / function claims notifications. After reviewing the notifications, the FDA sent 102 letters to manufacturers notifying them that the claims were not structure/function claims, but were disease claims not permitted for use in the labelling of dietary supplements. [31]

[31] CFSAN of the FDA, *CFSAN 2000 Program Priorities Report Card*, 5 December 2000, at http://vm.cfsan.fda.gov/~dms/cfsand00.html#part-ii.

PART 7 - ANALYSIS

23. Regulation of Dietary Supplements

23.1 Under DSHEA, dietary supplement manufacturers are responsible for ensuring that dietary supplements are safe before they are marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register with the FDA nor get FDA approval before producing or selling dietary supplements.

23.2 Although a dietary supplement manufacturer needs not obtain prior FDA review of structure / function claims carried by the dietary supplement product, he must possess substantiation that the claim is truthful and not misleading. He must also include a disclaimer in the product label.

24. Regulation of Imported Dietary Supplements

24.1 All imported dietary supplements are required to meet the same standard as domestic dietary supplements. The FDA may or may not examine the imported dietary supplement products upon the arrival of the shipment at the port of entry. The decision to examine a sample of the imported dietary supplements is made based on the following: (1) nature of the product, (2) FDA priorities and (3) past history of the product. If the FDA does not examine the products, the products are allowed to enter the US market. If the products are refused admission after an examination of the sample, the importer is required to either re-export or destroy the products.

24.2 Since there is no readily available information or statistics on the enforcement of the regulation of imported dietary supplements, therefore, we can only provide a description of the enforcement procedures but not an analysis of the enforcement of the regulations.

25. Lesser Regulation and Timely Market Access for Dietary Supplements

25.1 Under DSHEA, FDA's degree of control on the pre-market review of dietary supplements is lower than that over other products it regulates, such as drugs and many additives used in conventional foods.[32] This leads to a situation that consumers are able to have timely market access to a great variety of dietary supplements with the manufacturers of dietary supplements shouldering the responsibility for ensuring their products are safe.

26. Concerns Raised Regarding the Regulation of Dietary Supplements

Differentiation of Dietary Supplements from Conventional Food and Medicines

26.1 Prior to the enactment of DSHEA, dietary supplements were regulated either as foods or as drugs, depending on their intended use. If a product was used primarily for its taste, aroma, or nutritive value, it was regulated as a food. This meant that the safety of an ingredient used in a dietary supplement product had to be demonstrated before it could be marketed. If drugs claims were made by the product or the intended use of the product was as a drug, the product had to be subject to the regulation of drugs. That means the product had to meet the rigorous drug safety and efficacy requirements under the Federal Food, Drug and Cosmetic Act.

26.2 DSHEA created a new regulatory framework for dietary supplements that did not exist previously. The FDA has to delineate boundaries between dietary supplements, conventional foods and drugs. Without clear boundaries between these products, it would create difficulties for the FDA to enforce the law. For example, according to the statement made by the Commissioner of the FDA,[33] since the terms "dietary substance" and "intended to supplement the diet" contained in the definition of dietary supplements under DSHEA were broad, therefore, some products which contained substances similar to those found in prescription drugs were able to be marketed as dietary supplements. The FDA recognized this weakness and included this task of delineating boundaries between these products in its 10-year plan of Dietary Supplement Strategy (Appendix III). As of the date of the publication of this research report, the FDA has not come up with a clear differentiation of dietary supplements from conventional foods and drugs.

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[32] FDA, *An FDA Guide to Dietary Supplements*, January 1999 at http://www.fda.gov/fdac/features/1998/598_guid.html.

[33] *Statement* made by the Commissioner of Food and Drug Administration before the Committee on Government Reforms of the US House of Representatives dated 25 March 1999.

Claims Carried by Dietary Supplements

26.3 Since most disease treatments can be described in terms of their effects on a structure or function of the body, it is sometimes difficult to distinguish between allowable structure/function claims and prohibited drug claims.

26.4 Under DSHEA, dietary supplements would be able to claim to alter the structure or function of the body, but may not claim to cure, treat, prevent, mitigate or diagnose specific diseases - which are drug claims. The distinctions could sometimes be unclear. While "lowers cholesterol" would be considered as a drug claim (as elevated cholesterol level is considered as a characteristic of a disease), "maintaining a healthy lower cholesterol level" would be an acceptable statement of a structure / function claim for a dietary supplement. The difference between a drug claim or a health claim and a structure / function claim is therefore often a matter of semantics and consumers may not be able to distinguish it.

26.5 Furthermore, the evidence available to support structure / function claims varies widely because some ingredients have been thoroughly studied while others have not. For example, according to GAO[34], there is strong evidence in the medical literature that a herb named St John's Wort can be useful in treating mild depression. On the other hand, there is minimal evidence that ginseng may help to overcome fatigue. Yet, such claims are often made. Some structure / function claims such as "cleanses the blood", are so vague or general that it would be very difficult to prove.

Safety of Products

26.6 Unlike prescription or over-the-counter medicines, herbs and other dietary supplements do not have to undergo review for safety or effectiveness before they are marketed. Yet, some US consumer organizations consider that some "natural" products, like herbs, may have powerful pharmacological effects which could present risks for people who take other medications or who have specific medical conditions. They criticize that the current regulatory mechanism is not able to provide a sufficient degree of control over the safety of dietary supplements.

[34] US General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"*, July 2000 at http://www.gao.gov/.

26.7 Moreover, the process taken by the FDA to determine whether a safety problem exists, and to gather and assemble adequate evidence to support a regulatory action is often complex and time consuming. This is because in most cases dietary supplement manufacturers are not required to provide safety information to the FDA before marketing a product. The FDA has to gather information by itself before it can take action to restrict the sale of a dietary supplement product. This means that the FDA must rely on adverse event reports, product sampling, information in the scientific literature, etc. This process is often complex and time consuming.

27. Findings made by the US General Accounting Office

27.1 The GAO found weaknesses in three areas of the regulatory system of dietary supplements. First, potentially unsafe products may reach consumers for a variety of reasons, including the lack of a clearly defined safety standard for new dietary ingredients in dietary supplements (detailed in paragraph 11.4 above). Secondly, some products do not have safety related information on their labels, which might endanger some consumers (detailed in paragraph 14.3 above). Thirdly, the FDA cannot effectively assess whether a dietary supplement is adversely affecting consumers' health because, among other things, it does not investigate most reports it receives of health problems potentially caused by these products (detailed in paragraph 16.3 above).

27.2 These weaknesses had been recognized by the FDA as evidenced in its 10-year plan of Dietary Supplement Strategy (Appendix III). However, the plan did not state when or how the FDA would address these weaknesses.

Appendix I

List of FDA Authorized Health Claims

Health Claims	Attribute of Products	Can be used on labels of	
		Food	Dietary Supplements
Helps maintain healthy bones and may reduce risk of osteoporosis	High in calcium	✓	✓
May reduce risk of high blood pressure	Low in sodium	✓	
May reduce risk of some cancers, such as cancers of the breast, colon and prostate	Low in fat	✓	
May reduce risk of coronary heart disease	Low in saturated fat and cholesterol	✓	
May reduce risk of some cancers	Fibre containing fruits, vegetables, and grain products	✓	
May reduce risk of coronary heart disease	Fibre containing fruits, vegetables, and grain products	✓	
May reduce risk of some cancers	Fruits or vegetables	✓	
May reduce risk of brain and spinal cord birth defects	Supplying folic acid	✓	✓
May reduce risk of tooth decay	Uses dietary sugar alcohols	✓	
May reduce risk of heart disease	Contains soluble fibre from whole oats or psyllium husk	✓	✓
May reduce risk of heart disease	Contains soy protein	✓	✓

Sources:

1. US General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"*, July 2000, at http://www.gao.gov/
2. FDA, *FAQ: What are the FDA authorized health claims?* at http://vm.cfsan.fda.gov/~dms/qa-lab10.html.

Appendix II

Examples of Prohibited Claims and Allowable Claims Made About Dietary Supplements

Prohibited Claims	Allowable Claims
The product has an effect on a specific disease or class of diseases. E.g. ♦ "Protects against the development of cancer." ♦ "Reduces the pain and stiffness associated with arthritis."	Structure /function claims with no reference to a disease: ♦ "Helps promote urinary tract health." ♦ "Helps maintain cardiovascular function." ♦ "Promotes relaxation."
The product is in a drug class that is intended to be used to diagnose, mitigate, treat, cure, or prevent a disease. E.g. ♦ Description of a product as an "antibiotic", "antidepressant", or a "laxative", "vaccine", or "diuretic".	Product descriptions (with no reference to disease treatment or prevention): ♦ An "energizer"; ♦ A "rejuvenative".
The product has an effect on one or more recognizable signs or symptoms that are recognizable to health professionals or consumers as being characteristic of a specific disease or diseases. E.g. ♦ "Lowers cholesterol"; ♦ "Reduces joint pain".	Symptoms do not identify a disease: ♦ "Reduces stress and frustration"; ♦ "Improve absentmindedness".
The product is a substitute for, or augmentation of, a drug or other medical therapy. E.g. ♦ A suggestion that the product should be used "as part of your diet when taking insulin to help maintain a healthy blood sugar level".	

Prohibited Claims	**Allowable Claims**
The product has a role in the body's response to a disease or carrier of disease. E.g. ♦ "Supports the body's antiviral capabilities"; ♦ "Supports the body's ability to resist infection".	The product has an effect on a normal body function. E.g. ♦ "Supports the immune system".
The product has an effect on a consequence of a natural state that presents characteristic signs or symptoms recognizable as constituting an abnormality of the body. E.g. ♦ "Treats toxemia of pregnancy" or "treats Alzheimer's disease".	
The product treats, prevents or mitigates adverse events associated with a medical therapy or procedure. E.g. ♦ "Helps avoid diarrhea associated with antibiotic use." ♦ "Reduces nausea associated with chemotherapy."	The product does not mention any therapy or procedure, E.g. ♦ "Helps maintain healthy intestinal flora."

Source: *Fact Sheet: FDA's Dietary Supplement Proposal,* 27 April, 1998 at http://www.mlmlaw.com/library/guides/fda/ds-fact2.html

Appendix III

Dietary Supplement Strategy - Ten Year Plan

I. Safety

A. Adverse Event Reporting.

1. Systems Enhancement. Improve adverse event report monitoring system capability by enhancing the data systems and integrating them into the Agency-wide adverse event report monitoring system program.

2. Timely Release of Reports. Eliminate freedom of information act backlog and make reports available promptly to manufacturers on an ongoing basis.

3. Clinical Evaluation and Follow-Up. Institute an efficient system for the monitoring, clinical evaluation, and timely regulatory follow-up of significant adverse event reports.

4. Outreach. Educate consumers and health care professionals on how to use the adverse event reporting system.

B. Good Manufacturing Practices. Publish regulations on good manufacturing practices. Once the regulations are issued, establish an outreach program to small business manufacturers and an ongoing inspection program.

C. Health Hazard Evaluations. Enhance mechanisms for evaluating health hazards of dietary supplement ingredients and contaminants.

D. Dietary Supplement Safety Database. Explore development of a database to help anticipate health hazards.

E. New Dietary Ingredients.

1. Notifications. Continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

2. Guidance. Develop guidance for safety substantiation for premarket (75-day) notifications for new dietary ingredients.

3. Database. Incorporate the premarket (75-day) notifications in the comprehensive database created for claims notifications (see strategy item in II. C.).

F. Voluntary Submissions. Explore mechanisms for encouraging voluntary submissions of confidential premarket safety data to FDA (e.g., similar to procedural mechanisms for food additive master files).

G. Internet Surveillance. Implement an Internet surveillance program to monitor whether products are marketed for safe uses.

II. Labelling

A. Pearson v. Shalala. Implement court decision as outlined in December 1, 1999, strategy notice.

B. Health Claim Petitions. Meet statutory obligations by responding to health claim petitions within statutory timeframes.

C. Database. Complete and activate database for 30-day label claim notifications and courtesy letters.

D. Substantiation. Identify criteria for substantiation of structure/function and related claims and identify conditions for sharing substantiation documents.

E. Authoritative Statements. Publish final rule on the applicability to dietary supplements of the FDA Modernization Act provisions on nutrient content/health claim notifications based on authoritative statements.

F. Consumer and Marketplace Labelling Surveys. Perform surveys and track data of consumer purchases and marketing trends to support sound labelling policies.

G. Publications. Resolve issues on use of third-party publications.

H. Small Business Exemption. Resolve small business exemption issues for dietary ingredient claims.

III. Boundaries

A. Structure/Function Claims.

1. Final Rule. Publish a final rule on structure/function claims.

2. Small Business Regulatory Enforcement and Flexibility Act (SBREFA) Guidance. Following publication of final rule, issue SBREFA guidance.

3. Claims Review. Review 30-day postmarket notifications for supplement claims.

B. Dietary Supplement vs. Drug.

1. Definitions. Clarify the boundaries between dietary supplements and drugs by defining key terms and phrases (e.g., "dietary substance" and "intended to supplement the diet").

2. Claims. Clarify when a disease-related statement is an appropriate health claim for a dietary supplement, and when a disease claim is necessarily a drug claim.

C. Dietary Supplement vs. Conventional Food.

1. Definitions. Clarify boundaries between dietary supplements and foods by defining key terms and phrases (e.g., "intended for ingestion" and "represented for use as a conventional food") and clarifying the forms of dietary supplements.

2. Stakeholder Discussions. Coordinate and review stakeholder discussions addressing structure/function claims issues on conventional foods that may impact dietary supplement boundary issues (e.g., nutritive value).

D. Botanicals. Develop a regulatory framework for botanicals used in traditional/alternative medicine (including how they relate to over-the-counter drugs).

E. Dietary Supplement Exclusions. Clarify statutory provisions that exclude selling a product as a dietary supplement if the substance was first approved as a new drug under a New Drug Application or studied as an Investigational New Drug.

F. Dual Status. Clarify the regulation of dual status products (i.e., one substance intended for use as a supplement and a drug).

G. Combination Products. Clarify regulation of combination products (i.e., a supplement and a drug combined in a single dose, unit, or package).

H. Dietary Supplement vs. Cosmetic. Develop criteria for defining boundaries between products intended for cosmetic effect from dietary supplements.

IV. Enforcement Activities

In cooperation with the Office of Regulatory Affairs, and assisted, where appropriate, by other agency components:

A. Enforcement Strategy.

1. Safety Issues. Identify the highest priority safety issues and take appropriate action against unsafe products.

2. Boundary Issues. Take appropriate action on products excluded from being marketed as dietary supplements.

3. Labelling and Consumer Fraud. Take appropriate action on inaccurate and misleading labelling and consumer fraud, including trade complaints.

4. Routine Compliance. Maintain routine compliance activities, incorporating enforcement of final rules.

5. Surveillance and Monitoring. Conduct marketplace surveillance and monitoring activities.

6. Partnerships. Establish partnerships with federal, state and local agencies to enhance enforcement efforts by sharing data, heightening communication, and utilizing resources.

B. Capacity Building. Make necessary internal enhancements to effectively fulfill enforcement obligations.

1. Agency's Compliance Procedures. Develop standard operating procedures for improving the compliance review process.

2. Case Tracking System. Contract for and activate computerized dietary supplement case tracking system.

3. Training. Provide in-house training to field and headquarters staff to ensure consistency with current FDA regulatory procedures and practices.

4. CFSAN/CDER Coordination. Evaluate, and streamline, to the extent possible, current mechanisms for resolution of cross-center compliance issues.

5. Laboratory Capacity. Enhance analytical lab support for regulatory decisions.

C. Federal Trade Commission (FTC) Coordination. Enhance coordination with FTC on enforcement cases.

V. Science-Base

In collaboration with stakeholders (e.g., academia, health professionals, other organizations, and industry), enhance research/science capabilities, including:

A. Strengthen Science-Base. Ensure a sound science-based program for all dietary supplement review and develop a core of well-trained, multidisciplinary scientists in support of supplement review and research.

B. Strengthen Research Efforts.

1. Research Agenda. With the assistance of a nationally recognized organization, develop a broad research agenda and needs assessment framework to implement priority-based research for dietary supplement issues.

2. Research Capabilities.

a. Inventory and Peer-Review Process. Identify the Agency's scientific research capabilities relative to dietary supplements, and develop a mechanism for ensuring dietary supplement research is mission-relevant, of high scientific quality, and consistent with regulatory priorities.

b. Intramural/Extramural Research. Determine what research can or should be done by FDA (in-house) and what research should be done by extramural sources.

c. Laboratory Based Research. Conduct priority- based methods development and safety research for dietary supplement ingredients and contaminants.

3. Dietary Supplement Ingredient Reviews. Identify mechanisms for obtaining state-of-the-art science reviews on dietary ingredients in the marketplace, giving highest priority to those with potential health risks.

4. Leveraging. Identify leveraging opportunities with universities, JIFSAN, and other government agencies.

5. Consumer Research. Conduct research on consumer understanding of label information, and compare consumer understanding of labelling of conventional foods and dietary supplements for support of regulatory decisions.

6. Marketplace Research.

    a. Economics and Marketplace Research. Perform necessary economics and marketplace research for support of regulatory decisions.

    b. Market Analysis. Explore innovative mechanisms to determine the nature and scope of the dietary supplement market.

    c. Regulatory Oversight of Human Studies.

7. Oversight Mechanism. Clarify when an Investigational New Drug filing is necessary for a substance marketed as a dietary supplement and determine whether a separate mechanism needs to be developed for clinical studies on supplements.

8. Science-Based Standards. Develop science-based standards for conducting human studies of dietary supplements using human subjects.

D. Adverse Event Report Monitoring System. Conduct research to support enhancing and improving the quality and reporting rate of the adverse event report monitoring system and consider how the adverse event report monitoring system can be used for trend identification of adverse events.

E. Claims. Evaluate systems used in other organizations (e.g., health care reimbursement) to distinguish "valid substantiation" for claims (structure/function) from "invalid substantiation" for such claims.

F. Inter-agency Clearinghouse. Explore the establishment of an inter-agency dietary supplement research clearinghouse and develop an integrated list of information to be included.

VI. Outreach

Enhance outreach efforts to stakeholders to assure effective communication, including:

A. Advisory Committee. Establish a standing group to provide a routine public forum to obtain and integrate stakeholder input related to various dietary supplement issues. The group will be comprised of members having expertise relevant to the review of dietary supplement issues (e.g., subcommittee of the Food Advisory Committee).

B. Additional Stakeholder Outreach.

1. Public Forums. Sponsor and participate in public forums for enhancing dialogue with stakeholders.

2. Partnerships. Establish a stronger working relationship with organizations interested in promoting two-way communication and cooperation.

C. Communication.

1. Mechanisms. Develop mechanisms to communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. Website. Expand use of FDA website to communicate dietary supplement information to the general public and health care professionals, and guidance to the industry.

   b. Information Kits. Develop information kits for FDA field staff.

2. Information Dissemination. Communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. Safety Data.

   b. Enforcement Policies and Procedures.

Source: **http://vm.cfsan.fda.gov/~dms/ds-strat.html**.

References

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