用が強調表示の正当性を裏付ける水準で当該強調表示の提案者によって証明されたものでなければならず、FDA の要件を満たし、連邦食品・医薬品・化粧品法が適用できる食品安全性条項のもと、安全かつ合法であるものでなければならない。

(c) 妥当性の要件：FDA は、公的に入手可能な科学的根拠（広く認められた科学的手法と原理に合致する方法で行なわれた、優良な設計の研究から導かれた根拠など）の全体性に基づき判断する場合に限り、健康強調表示を承認する規定を施行するものとする。このような科学的根拠は、科学的な研鑽と経験から、当該強調表示の評価を行なうのに適任とされる専門家の間で明らかな科学的合意があり、このような根拠によって当該強調表示が支持されるものとする。

(d) 一般的健康強調表示の要件：

(1) 健康強調表示が本条のパラグラフ（c）の妥当性の要件を満たすと FDA が判断した場合、FDA は当該強調表示の使用を承認する本章 E 節の規定を提案するものとする。強調表示が 101.9 または 101.36 に該当する記載がない物質に関する場合、FDA は当該物質の申請を含めるよう当該規定を修正することを提案するものとする。

(2) FDA が本章 E 節の規定を修正した場合、企業は本章 E 節の規定に基づく強調表示を作成できる。ただし、次の条件に限る。

(i) 強調表示の対象である物質・疾病の関連性に関するすべてのラベルまたは表示の文言が、本章 E 節の規定において示される判定に基づくものであり、それと合致する場合。

(ii) 強調表示が総合的な食事パターンの一環として、当該物質の摂取（または上限量以下の摂取量）、特定の疾病または健康に関する状態に及ぼす可能性のある価値を述べることに限定される場合。

(iii) 強調表示に不備、偽りがなく、誤った印象を与えない場合。当該物質の食事摂取量以外の要素が当該物質および疾病または健康に関する状態との関連性に影響を与える場合は、本章 E 節の特別規定により、当該要因を強調表示の中で述べるよう求められることがある。

(iv) 強調表示に含めるよう求められるすべての情報が、妨げになる他の資料

を排除して１箇所に表示される場合。ただし、ラベルまたは表示の主要な表示パネルに参照を示す文言「____と____との関連性に関する情報は____を参照のこと」という表示が入る場合、またはこの空欄に健康強調表示、物質名、およびこれ以外の表示の別の箇所に見られるすべての強調表示の疾病または健康に関する状態（「カルシウムと骨粗鬆症に関する情報は添付のパンフレットを参照のこと」など）など表示の該当箇所を充当する場合を除く。ただし、ラベルまたは表示にある明示的または暗示的な健康強調表示を構成するいかなる図形表現（心臓のシンボルなど）も、参照を示す文言または全強調表示がその図形表現に直近の位置に表示されなければならない。

(v)　強調表示が、一般消費者にとって記載された情報の内容を把握し、日常の食事全般に照らして当該情報の相対的な重要性を理解できるものである場合。

(vi)　強調表示が、物質を上限量以下の摂取量で摂取する効果に関するものであるなら、食品に含まれる当該物質の水準は強調表示の正当性を裏付けるのに十分なほど低い場合。この要件を満たすため、「低い」という語の使用定義が、本章に従い当該物質に対して定められた場合、本章Ｅ節において物質に対するこれに代わる特別な水準が設定された場合を除き、この用語の使用要件を満たす水準で含有されなければならない。「低い」の定義がない場合、当該物質の水準は、当該強調表示を承認する規定において定められた水準を満たさなければならない。

(vii)　強調表示が、物質を上限量以下の摂取量以外で摂取するときの効果に関するものなら、物質の水準が十分に高く、強調表示の正当性を裏付けるのに適切な形式である場合。この要件を満たすため、物質に対する「高い」という用語の使用定義が本章に従って決められた場合、本章Ｅ節において物質に対するこれに代わる特別な水準が設定された場合を除き、当該物質はこの用語の使用要件を満たす水準で含有されなければならない。「高い」の定義がない場合（強調表示がホールフードまたは他の食品の成分として、ある食品に関係がある場合など）、強調表示は当該強調表示を承認する規定において定められたとおり、強調表示にある効果を獲得するために必要な１日摂取量を特定しなければならない。ただし、次の条件に限る。

(A)　本条のパラグラフ（d）(2)（vi）または（d）(2)（vii）の要件を満

たす強調表示が日常的摂取基準量当たりで記載された食品、および表示された1回摂取量がこの基準量とは異なる場合、当該強調表示の後に、その強調表示に表示された1回摂取量ではなく、この基準量に基づくものであることを説明する文言を追加しなければならない（「低ナトリウム食事療法は、多くの要因に関連する疾病、高血圧のリスクを軽減する可能性があります。本製品を_オンス摂取することは、規定に定められた1回の摂取量に準拠しています。」など）。

(B) 強調表示を記載した食品が、飲食施設またはヒトがすぐに摂取できる状態の食品が販売されるその他の施設において販売される場合、当該食品を販売する企業は、強調表示を記載した食品が本条のパラグラフ（d）（2）（vi）または（d）（2）（vii）の要件を満たすと考える論理的な根拠をもち、要請に応じてその根拠を提供する場合、当該食品が本条のパラグラフ（d）（2）（vi）または（d）（2）（vii）の要件を満たすものとしてよい。

(3) 101.9に従って健康強調表示を作成する対象となるすべての食品（ただし、飲食施設の食品の場合は101.10、サプリメントの場合は101.36に従う）には、栄養表示をラベルまたは表示に記載しなければならない。

(e) 禁止健康強調表示：以下の条件に該当しない場合、食品が一般食品の形態であるかサプリメントの形態であるかにかかわらず、食品向けのラベルまたは表示の、明示的または暗示的な健康強調表示を作成してはならない。

(1) 強調表示が、本章E節において特別に規定されたものの場合。および、

(2) 強調表示が、本条の一般条項すべて、および本章E節に該当する条の特別条項すべてに準拠する場合。

(3) 本条のパラグラフ（a）（4）において規定されるすべての食品における不適格な水準を超えない場合。ただし、本章E節において物質に対するこれに代わる特別の水準が設定された場合、またはFDAが、当該強調表示が消費者の健康的な食事習慣の維持に役立つという結果、およびそのような結果をもたらす本章E節の規定に従って、その栄養素が不適格な水準を超えていることを特記する101.13（h）に従った開示説明書がラベルに含まれることに基づき、栄養素が食品中に含まれる水準が不適格である事実にもかかわらず強調表示を認可した場

合はこの限りでない。

(4) 本条のパラグラフ（e）(3) に記載された場合を除き、本章E節において強調表示を承認する特定条項において規定された不適切な水準で含まれていない場合。

(5) 本章E節において特別に記載された対象である場合を除き、その食品が2歳未満の乳幼児向けであることを表わすものでない、またはそのような趣旨ではないラベルの場合。および、

(6) サプリメント向けまたは第101章E節における他の規定の対象でない限り、食品が他に栄養素の添加がない状態で日常的摂取基準量当たりのビタミンA、ビタミンC、鉄分、カルシウム、タンパク質、または食物繊維に対する基準1日摂取量または1日基準量の10パーセント以上を含有する場合。

(f) 本条の要件が適用できないものは以下のとおり。

(1) 連邦食品・医薬品・化粧品法の第412条（h）に従う、乳児向けフォーミュラおよび、

(2) 希少疾病用医薬品法の第5条（b）に定義された医療用食品。

(g) 適用の範囲：本条の要件は、食品が一般食品の形態かサプリメントの形態かにかかわらず、ヒトが摂取する用途で市販される食品に適用される。

US-Japan Symposium

Trends in Food Function and Labeling

Sponsored by:
Health and Labour Sciences Research Grants, Research on Food Safety,
Research Project (Principal Investigator: Nobuaki Shibaike)
&
Incorporated Administrative Agency, National Institute of Health and Nutrition (NIHN)

Date: December 1, 2008

Location: National Institute of Health and Nutrition (NIHN), Tokyo, Japan

日米シンポジウム

食品の機能と表示の最新動向

主催:
厚生労働科学研究費補助金(食品の安心・安全確保推進研究事業)
「特定保健用食品等の有効性・安全性を確保するための
科学的根拠の評価方法に関する研究」 研究班
(研究代表者　芝池 伸彰)

共催: 独立行政法人 国立健康・栄養研究所

開催日:平成20年12月1日
会場: 独立行政法人 国立健康・栄養研究所

Trends in Food Function and Labeling

US-Japan Symposium, December 1, 2008

National Institute of Health and Nutrition, NIHN

Dear Conference Participant,

On behalf of the National Institute of Health and Nutrition in Japan, we would like to welcome you to this symposium entitled "Trends in Food Function and Labeling." The goal of this symposium is to critically evaluate the difference between the USA and Japanese systems related to food function and labeling. Presentations will cover a range of topics in order to further our knowledge and understanding about the role of health food and dietary supplements. Time will be available for questions throughout the conference. Open discussion is scheduled at the end of meeting to discuss the system between USA and Japan. Your comments during the workshop will contribute to our efforts to explore the next steps.

We look forward to a stimulating and informative meeting!

Sincerely yours,

Nobuaki Shibaike, M.D.
Principal Investigator

Kazuhiko Yamada, Ph.D.
Co-Investigator

Keizo Umegaki, Ph.D.
Co-Investigator

Nobuyo Tsuboyama-Kasaoka, Ph.D., R.D.
Co-Investigator

Health and Labour Sciences Research Grants,
Research on Food Safety,
Research Project

PROGRAM

プログラム

Trends in Food Function and Labeling

US-Japan Symposium, December 1, 2008

National Institute of Health and Nutrition, NIHN,
First Conference Room

Agenda

Coordinator: Nobuyo Tsuboyama-Kasaoka (NIHN, Japan)

13:00 -13:10	Introduction	Nobuaki Shibaike (Executive Director, NIHN, Japan)
13:10 -13:30	Welcome	Shaw Watanabe (Director-General, NIHN , Japan)
	Moderator: Keizo Umegaki (NIHN, Japan)	
13:30-14:30	Paul M. Coates (Director, Office of Dietary Supplement, NIH, USA) **Dietary Supplements in the United States: Claims and Evidence**	
14:30 -14:40	Questions	
14:40-15:00	Break	
	Moderator: Yoshiko Ishimi (NIHN, Japan)	
15:00 -16:00	John A. Milner (Chief, Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute, NIH, USA) **Nutrigenomics and Bioactive food components**	
16:00-16:10	Questions	
	Moderator: Toyonori Omori (NIHN, Japan)	
16:10 -16:40	Jun Tamagawa (Director, Office of Health Policy on Newly Developed Foods Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare , Japan) **Health claim and FOSHU system in Japan**	
16:40-16:50	Questions	
	Moderator: Kazuhiko Yamada (NIHN, Japan)	
16:50-17:20	**Open Discussion**	
17:20 -17:25	Summary & Conclusions	Toyonori Omori (Director for Research Coordination and Evaluation, NIHN, Japan)
17:25	Adjourn	

日米シンポジウム
食品の機能と表示の最新動向

独立行政法人　国立健康・栄養研究所　共用第一会議室
平成20年12月1日

プログラム

総合司会……（独）国立健康・栄養研究所　調整担当上級研究員　笠岡（坪山）宜代

12:30-　開 場

13:00-13:10　開会挨拶……（独）国立健康・栄養研究所　理事　芝池　伸彰

13:10-13:30　挨拶「食品保健と研究所の取り組み」……（独）国立健康・栄養研究所　理事長　渡邊　昌

座長：梅垣敬三（(独)国立健康・栄養研究所　情報センター長）

13:30-14:30　米国の健康強調表示とサプリメント……Director, Office of Dietary Supplement, National Institutes of Health (NIH), USA　Paul M Coates

14:30-14:40　質疑応答

14:40-15:00　休 憩

座長：石見佳子（(独)国立健康・栄養研究所　生体指標プロジェクトリーダー）

15:00-16:00　ニュートリゲノミクスと食品成分…… Chief, Nutritional Science Research Group, National Cancer Institute, NIH, USA　John A. Milner

16:00-16:10　質疑応答

座長：大森豊緑（(独)国立健康・栄養研究所　研究企画評価主幹）

16:10-16:40　日本の特定保健用食品制度と食品表示……厚生労働省 医薬食品局食品安全部 新開発食品保健対策室　室長　玉川　淳

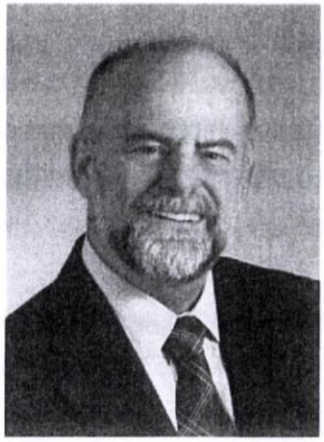
16:40-16:50　質疑応答

座長：山田和彦（(独)国立健康・栄養研究所　食品保健機能プログラム　プログラムリーダー）

16:50-17:20　オープンディスカッション

17:20-17:25　閉会の辞……（独）国立健康・栄養研究所　研究企画評価主幹　大森　豊緑

17:25　閉 会



Paul M. Coates, Ph.D.
Director, Office of Dietary Supplements (ODS), National Institutes of Health (NIH)

Dr. Paul Coates has directed the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) since October 1999 in its mission to strengthen knowledge and understanding of dietary supplements. He oversees a range of initiatives and programs that support research and the training of investigators and also lead to the development of information resources and tools. Under Dr. Coates' leadership, the ODS budget had grown eightfold, from $3.5 million in 1999 to nearly $28 million in 2008. He has established ODS as a strong and authoritative voice for rigorous research. As the ODS spokesperson, he has presented at many national and international scientific meetings and is frequently interviewed by the media to increase the knowledge of dietary supplements among diverse audiences.

In related work, Dr. Coates serves as a member of the Federal Steering Committee that oversees the development of nutrient recommendations for the public known as Dietary Reference Intakes. He is also the lead editor of the authoritative *Encyclopedia of Dietary Supplements* published by Marcel Dekker in 2006.

Prior to his tenure at ODS, Dr. Coates served from 1996-1999 as Deputy Director of the Division of Nutrition Research Coordination (DNRC) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In that role, he coordinated human nutrition research efforts at the NIH and between NIH and other government agencies. Among these efforts was *Healthy People 2010*, the initiative from the U.S. Department of Health and Human Services (DHHS) to set public health goals for the nation. Dr. Coates co-led production of the chapter on "Nutrition/Overweight," for which he received the NIH Director's Award for outstanding activities. Dr. Coates was also Co-Chair of the Joint DHHS/USDA (U.S. Department of Agriculture) Steering Committee that planned the National Nutrition Summit held in Washington, D.C. in May 2000.

Before joining the DNRC, Dr. Coates was NIDDK's Program Director for the Type 2 Diabetes Research Program (1993-1996) and Project Officer for the multi-center clinical study known as Epidemiology of Diabetes Interventions and Complications (1994-1996). In 1994-1996, he was also involved in career development and fellowship training in the Division of Diabetes, Endocrinology, and Metabolic Diseases.

From 1975 to 1993, prior to his career at NIH, Dr. Coates served on the faculty of the Children's Hospital of Philadelphia as well as the University of Pennsylvania School of Medicine as Research Professor in the Departments of Pediatrics and Biochemistry/Biophysics. His Ph.D. in human genetics was awarded by Queen's University in Canada (1972) followed by postdoctoral training in the Department of Human Genetics and Biometry at University College London (1972-1974).

Dr. Coates' major research interests for many years focused on inborn errors of human lipid metabolism, an area where he conducted some of the first studies of fatty acid oxidation disorders in infants and children. With an international team of collaborators, he defined many of the genetic defects of human mitochondrial fatty acid oxidation. Dr. Coates has also has studied the metabolism of intestinal and hepatic lipoproteins to identify the metabolic defects in inherited hyperlipidemias. These studies have led to a new understanding of the role of environmental factors, such as diet, in the manifestation of genetic diseases. Dr. Coates has published more than 100 scientific papers and has edited two books in these areas of research.

Coates PM, Blackman M, Cragg G, Levine M, Moss J, White J (editors): Encyclopedia of Dietary Supplements. New York: Marcel Dekker, 2005.

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Dietary Supplements in the United States:

Claims and Evidence

The National Institute of Health and Nutrition
December 2008

Paul M. Coates, Ph.D.
Office of Dietary Supplements
National Institutes of Health
Department of Health and Human Services

Overview

Evening Primrose
Oenothera biennis

- A Brief History of Dietary Supplements
- The US Environment for Health Claims
- The Office of Dietary Supplements (ODS)
- Issues in Dietary Supplement Research

DSHEA

(Dietary Supplement Health and Education Act - 1994)

- Amended the Food, Drug & Cosmetic Act
- Defined dietary supplements
- Established regulatory framework
  - Food and Drug Administration (FDA)
  - As foods, not as drugs
- Established rules for what a label should contain
- Gave FDA authority to write GMPs
- Called for creation of the Office of Dietary Supplements at the NIH

Dietary Supplement: DSHEA Definition

Product intended to supplement the diet

Contains one or more of the following:

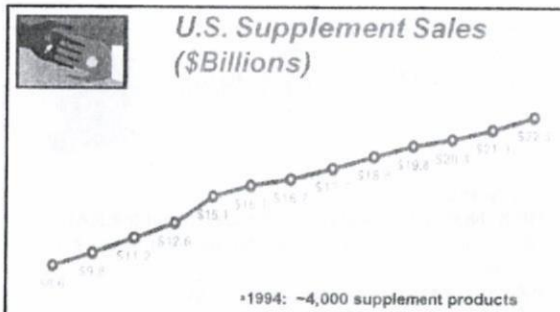
- Vitamin
- Mineral
- Herb or other botanical *(not tobacco)*
- Amino acid
- Other dietary substance

Regulation of Dietary Supplements in the United States

Rules for
foods, *not drugs*,
apply to dietary supplements

An ingredient is presumed safe based on its history of use in humans

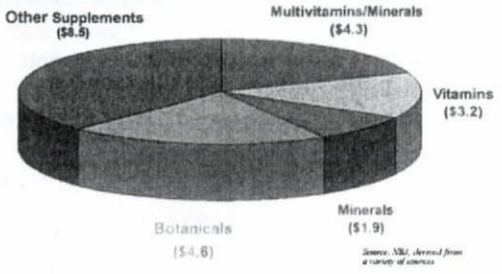
U.S. Supplement Sales ($Billions)



- 1994: ~4,000 supplement products
- 2008: ~75,000?

*Source: Nutrition Business Journal

Dietary Supplement Sales in 2006: $22.5 Billion



Top 10 Dietary Supplements for 2006

Multivitamins/minerals
Calcium
B vitamins
Vitamin C
Glucosamine/Chondroitin
Fish oils
Vitamin E
Coenzyme Q10
Vitamin A
Probiotics

Nutrition Business Journal

Botanicals

Phytomedicines



Foods of plant origin



Types of Claims

Health claims

Nutrient content claims

Qualified health claims

Structure/function claims

Basis for Claims

Congress
1990: Nutrition Labeling and Education Act (NLEA)
1994: Dietary Supplement Health and Education Act (DSHEA)
1997: FDA Modernization Act (FDAMA)

Case law (judiciary)

Rules and regulations by FDA & FTC

Justifications for Allowing Claims

- Encourage consumption of good foods
- Allow for food comparisons
- Provide "level playing field"
- Incentive to manufacture better food products

NLEA: Health Claim

- Substance
  - Food: apple
  - Component: folic acid
- Disease
  - Cancer
- Health-related condition
  - High cholesterol

Evaluating the Science

- Standard of evidence: significant scientific agreement (SSA)
  - Quantity of studies
  - Methodological quality
  - Study outcomes
  - Consistency of relationship
  - Relevance to US population

FDA Approved Health Claims

- Calcium & osteoporosis*
- Sodium & hypertension*
- Saturated fat & cholesterol & CHD*
- Lipids (fats) & cancer*
- Fruits, veggies & fiber-containing grains & CHD*
- Fruits & veggies & cancer*
- Fiber-containing grains, fruits & veggies & cancer*
- Folic acid & NTDs*
- Non-cariogenic carb. sweeteners & dental caries
- Soluble fiber & CHD
- Soy protein & CHD
- Plant stanol/sterols & CHD

Health Claim: Calcium & Osteoporosis

- FOOD OR SUPPLEMENT
  - High in calcium
  - Bioavailable
  - Pills must disintegrate & dissolve
  - Amount of calcium > phosphorus
- CLAIM REQUIREMENTS
  - Disease depends on many risk factors
  - Primary target population
  - Additional factors to reduce risk

Mechanism of link: optimize peak bone mass

If >400mg calcium, note that intakes >2,000mg provided no added bone benefit

MODEL CLAIM

- Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Health Claims Based on Authoritative Statements

- Allowed by 1997 FDAMA (Food and Drug Administration Modernization Act)
- Statements from government scientific bodies or NAS
- FDA given 120 days to evaluate a petition for a claim
- Not for supplements!
- Whole grains & CHD & certain cancers
- Potassium & high blood pressure & stroke
- Fluoride & dental caries
- Saturated fat & cholesterol & trans fat & CHD
- Substitution of saturated fat with unsaturated fatty acids & CHD

NLEA: Nutrient Content Claims

- "Core" claims:
- free, low, lean, extra lean, high, good source, reduced, less, light, fewer, more

- Nutrients
- "Good": 10-19% DV
- "Rich", "Excellent," "High": ≥20% DV

Nutrient Content Claim: "High Potency"

- For single nutrient:
- ≥100% recommended intakes

- For multiple nutrients
- >2/3 at ≥100% recommended intakes

"Qualifying" Health Claims

- SSA disallows free speech?
- 1999 Pearson v. Shalala
- Permit potentially misleading claims using qualifying language
- "Disclosure over suppression"

"Consumer Health Information for Better Nutrition Initiative"

Scientific Ranking	FDA Category	Appropriate Qualifying Language
First level	A	None; SSA; a true health claim
Second level	B	"...although there is scientific evidence supporting the claim, the evidence is not conclusive
Third level	C	"Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive"
Fourth level	D	"Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim"

Qualified Health Claims: FDA "Enforcement Discretion"

- 0.8 mg folic acid & neural tube defects
- B vitamins & vascular disease
- Selenium & cancer
- Antioxidant vitamins & cancer
- Phosphatidylserine & cognitive dysfunction & dementia
- Nuts & heart disease
- Walnuts & heart disease
- Omega-3 fatty acids & CHD
- Monounsaturated fatty acids from olive oil & CHD
- Green tea & cancer
- Chromium picolinate & diabetes
- Calcium & colon/rectal cancer Calcium & recurrent colon/rectal polyps
- Calcium & hypertension, pregnancy-induced HBP & preeclampsia
- Tomatoes and/or tomato sauce & prostate, ovarian, gastric, and pancreatic cancers
- Unsaturated fatty acids from canola oil and reduced risk of CHD
- Corn oil and corn-oil containing products and a reduced risk of heart disease

Qualified Health Claim: Chromium Picolinate & Diabetes

- "One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."

DSHEA "Statements of Nutritional Support"

Structure/function claims

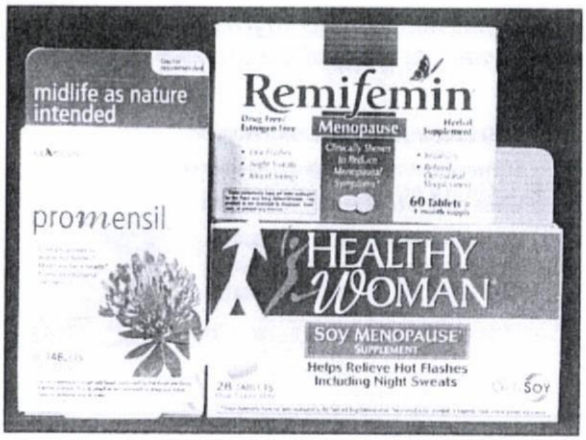
Describes role of ingredient or its mechanism "intended to affect the structure or function in humans"

Must not claim to "diagnose, mitigate, treat, cure, or prevent" disease

Manufacturer has substantiation that statement is "truthful and not misleading"

Does not require prior FDA approval

Must include disclaimer on label



Structure/Function vs. Disease Claims

Structure/Function Claims	Disease Claims
Helps maintain normal cholesterol levels	Lowers cholesterol
Maintains healthy lung function	Maintains healthy lung function in smokers
Provides relief of occasional constipation	Provides relief of chronic constipation
Suppresses appetite to aid weight loss	Suppresses appetite to treat obesity
Supports the immune system	Supports to body's antiviral capabilities
Relief of occasional heartburn or acid indigestion	Relief of persistent heartburn or acid indigestion
For relief of occasional sleeplessness	Helps reduce difficulty in falling asleep
Arouses sexual desire	Helps restore sexual vigor, potency, performance

Health-Related Claims: Clear or Confusing?

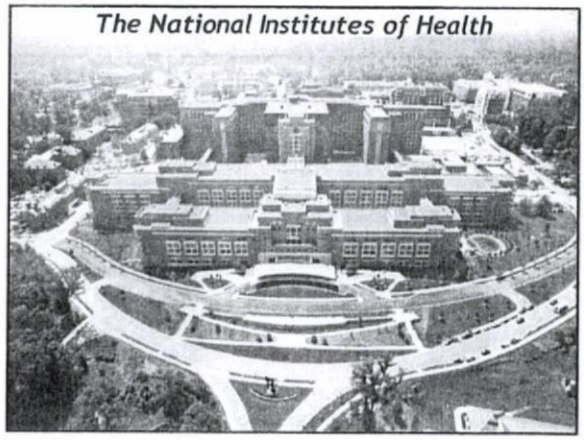
- **Always a debate**
  - **Health professionals vs. food industry**
- **Remarkably little study**
  - **2005 survey by Intl. Food Information Council (IFIC)**
  - **2007 FDA survey**
- **Different types of claims**
  - **Different levels of scientific rigor**

"Avoid food products that make health claims"

MICHAEL POLLAN

Office of
Dietary Supplements
National Institutes of Health

The National Institutes of Health



NIH is the Nation's Medical Research Agency

- 27 Institutes and Centers
- Total NIH Budget for 2008: $28 billion
- Grants, Contracts, Cooperative Agreements
- Department of Health & Human Services
  - Along with FDA, CDC and other agencies

www.nih.gov

ODS Mission Is to Strengthen Knowledge and Understanding of Dietary Supplements

- Evaluate Scientific Information
- Stimulate and Support Research
- Disseminate Research Results
- Educate the Public to Foster an Enhanced Quality of Life and Health for U.S. Population

Echinacea
Echinacea purpurea

ODS Evidence-Based Review Program

- Systematic review of the literature, with meta-analysis as appropriate, on DS efficacy and safety
- Major reason for conducting these reviews is to assist NIH in the development of research agendas
- Examples: omega-3 fatty acids, soy, vitamin D

Evidence

- Pre-Clinical
- Ecologic
- Observational
- Cohort
- Intervention
- RCT

Dietary Supplement Research: Product Concerns

- Identification
- Characterization
- Reproducibility

Black Cohosh
Cimicifuga racemosa L.

Dietary Supplement Research: Protocol Concerns

- Population(s)
  - Generalizability
- Endpoints
- Dose
- Earlier Phase Studies

Red Clover
Trifolium pratense

Current Issues

- **Trials of single ingredients or combinations**
  - **SELECT**
  - **Ginkgo biloba**
  - **Antioxidant vitamins**
- **Dietary Reference Intakes**
  - **Vitamin D and Calcium**

Office of
Dietary Supplements
National Institutes of Health

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John A. Milner, Ph.D.
Chief, Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute (NCI), National Institutes of Health (NIH)

John Milner, Ph.D., is chief of the Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute. From 1989 to 2000, he was Head of and a Professor in the Department of Nutrition at The Pennsylvania State University, where he also served as Director of the Graduate Program in Nutrition. Before joining Penn State, he was a faculty member for 13 years in the Food Science Department and in the Division of Nutritional Sciences at the University of Illinois-Urbana-Champaign. While at the University of Illinois he served as the Director of the Division of Nutritional Sciences and as an Assistant Director of the Agricultural Experiment Station.

Dr. Milner earned a Ph.D. from Cornell University in nutrition, with a minor in biochemistry and physiology and a B.S. in Animal Sciences from Oklahoma State University. Dr. Milner is a member of several professional organizations, including the American Society for Nutrition, American Association of Cancer Research, American Chemical Society's Food and Chemistry Division, the Institute of Food Technology and the International Society of Nutrigenetics/Nutrigenomics. He is a fellow in the American Association for the Advancement of Science and an Honorary Member of the American Dietetic Association.

He has served in an advisory capacity as a member of the U.S. Department of Agriculture's Human Nutrition Board of Scientific Counselors, Joint USDA/HHS Dietary Guidelines

Committee, and for the Food, Nutrition and Safety Committee within the International Life Sciences Institute (ILSI). Dr. Milner has served as president of the American Society for Nutrition (formerly the American Institute of Nutrition) and has testified before the Subcommittee on Appropriations in Washington, D.C. and the Presidential Commission on Dietary Supplement Labels in Baltimore, Maryland. He has served as a member of the National Academy of Sciences Committee on Military Nutrition Research, the U.S. Olympic Committee Dietary Guidelines Task Force, the External Advisory Board for the Pennington Biomedical Research Center, as a member and Vice-Chair for the Counsel of Experts of United States Pharmacopeia Committee on Bioavailability and Nutrient Absorption and a member of the External Advisory Board for the European Commission SeaFood Plus initiative. He is currently a member of the Global Board of Trustees for ILSI, liaison to the International Food Information Council (IFIC) member of the Danone Institute's International Functional Foods and Health Claims Knowledge Center Committee, and chair of the World Cancer Research Fund/American Institute for Cancer Research Mechanisms Working Group.

Dr. Milner has published more than 200 book chapters, monographs and journal articles. He serves on the editorial boards for *Cancer Prevention Research*, *Food and Nutrition Research, Nutrition and Cancer, Nutrfood, Journal of Nutritional Biochemistry, Journal of Alternative and Complementary Medicine, Journal of Ovarian Research*, *and The Journal of Medical Foods*. In his current position he promotes research that deals with the physiological importance of dietary bioactive compounds as modifiers of cancer risk and tumor behavior. Much of his own current research focuses on the anticancer properties of garlic and associated allyl sulfur compounds. In addition to presentations about nutrigenomics he has been an invited to speak about garlic and health, selenium nutriture, antioxidants and health, functional foods and health promotion, and nutrition for cancer prevention.