AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION
1982 celebrating 2022 40

40 Years of AHPA: A Timeline of Preserving Health Freedom

Panel Discussion

March 9, 2022

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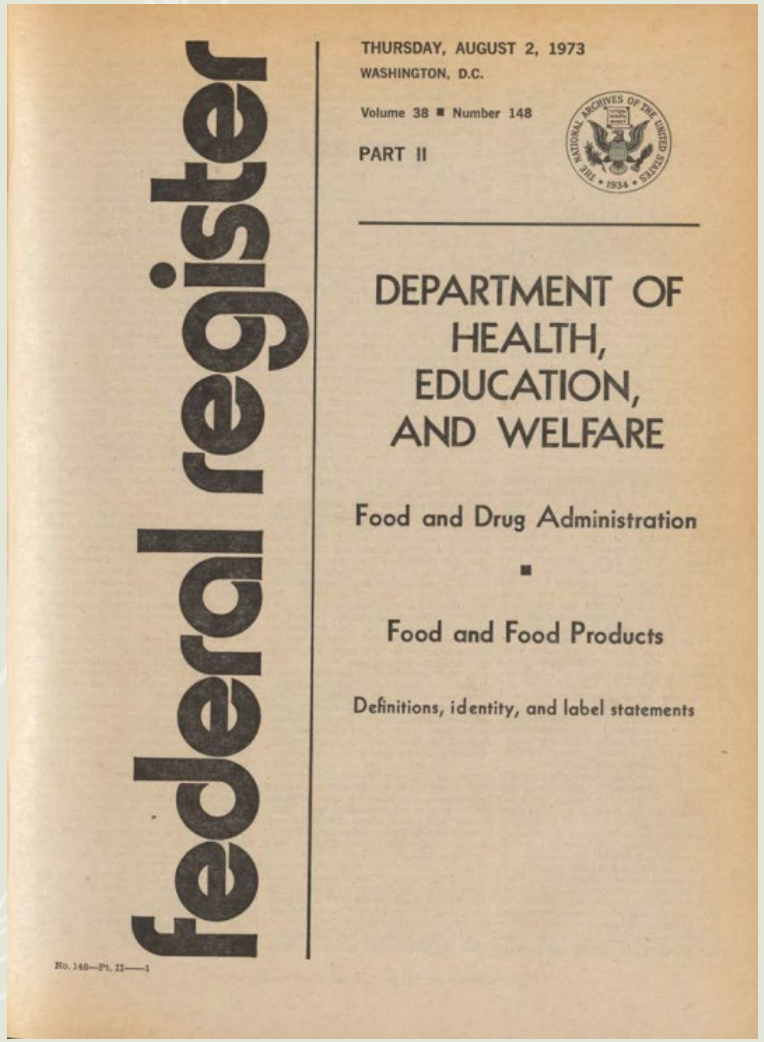
Federal Register Vol. 38, No. 148 (August 2, 1973)



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THURSDAY, AUGUST 2, 1973
WASHINGTON, D.C.

Volume 38 ■ Number 148

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

Food and Food Products

Definitions, identity, and label statements

No. 148—Pt. II——1

U.S. Government Recommended Daily Allowances (U.S. RDA's) and Permissible Compositional Ranges for Dietary Supplements of Vitamins and Minerals

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA'S) AND PERMISSIBLE COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of Measurement	Children under 4 years of age [1]—U.S. RDA			Adults and children 4 or more years of age—U.S. RDA			Pregnant or lactating women—U.S. RDA		
		Lower Limit		Upper Limit	Lower Limit		Upper Limit	Lower Limit		Upper Limit
Vitamins										
Mandatory										
Vitamin A	International Units	1,250	2,500	2,500	2,500	5,000	5,000	5,000	8,000	8,000
Vitamin D [2]	do	200	400	400				400	400	400
	do	5	10	15	15	30	45	30	30	60
Vitamin C	Milligrams	20	40	60	30	60	90	60	60	120
Folic acid [3]	do									
Thiamine	do	0.35	0.70	1.05	0.75	1.50	2.25	1.50	1.70	3.00
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10.0	20.0	30.0	20.0	20.0	40.0
Vitamin B_6	do	0.35	0.70	1.05	1.00	2.00	3.00	2.00	2.50	4.00
Vitamin B_{12}	Micrograms	1.5	3.0	4.5	3.0	6.0	9.0	6.0	8.0	12.0
Optional										
Vitamin D	International Units				200	400	400			
Biotin [4]	Milligrams	0.075	0.150	0.225	0.150	0.300	0.450	0.300	0.300	0.600
Pantothenic acid	do	2.5	5.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Minerals										
Mandatory										
Calcium	Grams	0.125	0.800	1.200	0.125	1.000	1.500	0.125	1.300	2.000
Phosphorus [5]	Do	0.125	0.800	1.200	0.125	1.000	1.500			
Iodine	Micrograms	35	70	105	75	150	225	150	150	300
Iron	Milligrams	5	10	15	9	18	27	18	18	60
Magnesium	Do	40	200	300	100	400	600	100	450	800
Optional										
Phosphorus [5]	Grams							0.125	1.300	2.000
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	Do	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0

[1] When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this column nor more than 100% of the infant U.S. RDA for a nutrient as prescribed in §125.1(b) except that the level of biotin, when used shall be 0.05 mg per daily recommended quantity.
[2] Optional for adults and children 4 or more years of age.
[3] Optional for liquid products.
[4] Lower limit may be 0.05 milligram until December 31, 1976.
[5] Optional for pregnant or lactating women. When present, the quantity of phosphorus may be no greater than the quantity of calcium.

Upper Limit: 90 mg of Vitamin C for adults and children 4 or more years of age

FDA Consumer Magazine (1983)

Herbs Are Often More Toxic Than Magical

by Tim Larkin

herb (ərb, hurb) **n.** [ME. *erbe, herbe* < OFr. < L. *herba,* grass, herbage, herb] 1. As commonly used, the term "herb" is not restricted to the botanical definition of a seed-producing plant as being an annual, biennial or perennial with a nonwoody stem, which dies down at the end of a growing season. The Herb Trade Association considers herbs to be "... plants or plant parts which are extracted or dried and valued for their savory, aromatic or other qualities."

Some words are brimful of magic: gold, silver, nectar, paradise, jewel, check enclosed. Certainly qualified for admission into this company is another glittering word: herb. Indeed, "herb" may actually outshine precious metals and gems in its power to evoke magical connotations. After all, gold, silver and precious stones merely enrich or beautify; nectar only titillates the tastebuds; and paradise still eludes us. But herbs not only sprinkle magic upon otherwise insipid food; they were, for centuries, the physician's primary source of help for the sick. Perhaps that is why herbs outnumbered gold two to one among the gifts bestowed by the Three Wise Men.

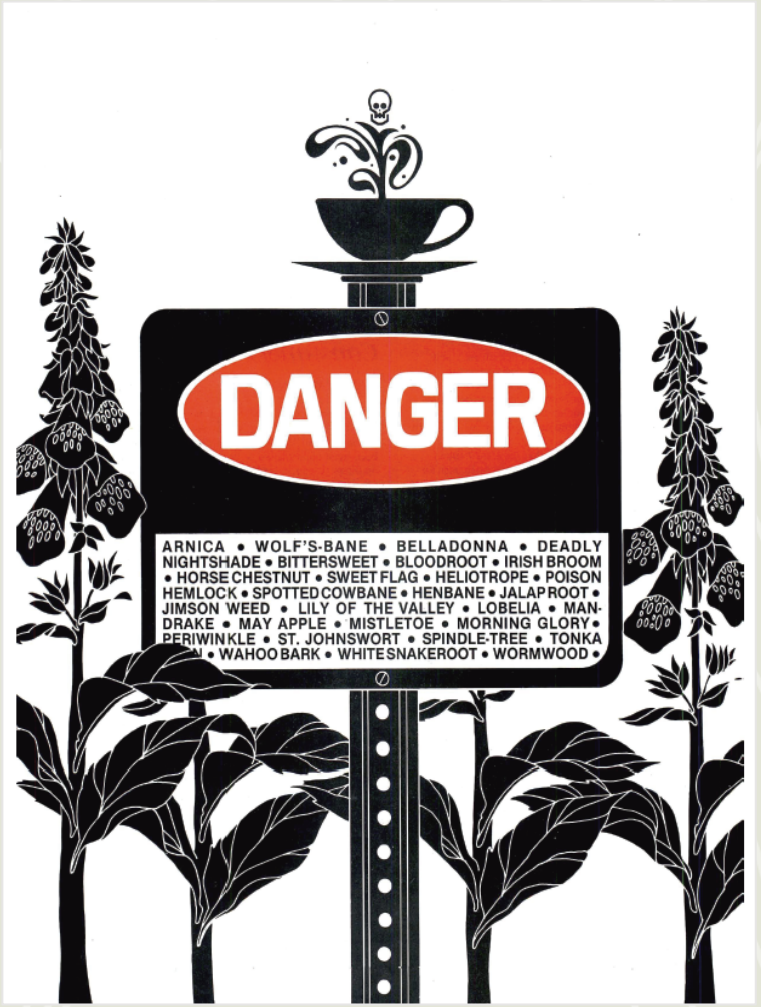
Attesting to the importance of herbs to people throughout history is the fact that among the writings remaining to us from the ancient civilizations of Sumer, Assyria, Egypt, Greece, China and Rome are "herbals": manuals that help identify plants believed to possess medicinal qualities. These herbals show clearly that thousands of plants, from absinthe (*Artemisia absinthium*—wormwood) to yarrow (*Achillea millefolium*—milfoil), have, from the dawn of history, been considered medicines with the power to cure or alleviate a host of afflictions. The famous "Ebers Papyrus," written some 35 centuries ago, contains the herbal remedies used by an unknown Egyptian physician. Dioscorides, a surgeon in the army of the Roman Emperor Nero, made the first comprehensive list, or *materia medica*, of all known medicinal herbs. This list was modified and expanded through the centuries, with many entries finding their way into official lists of drug formulas such as the *U.S. Pharmacopeia*. In the early years of the 20th century the more scientific approach eliminated most of these herbal compounds as ineffective. Others, such as quinine from the bark of the cinchona plant (*Cinchona calisaya*), have been replaced gradually by synthetic compounds that do the job more effectively.

Since the role of herbs in modern medicine has been reduced almost to the vanishing point, it would seem logical to conclude that their magic also would disappear. But, like so many conclusions that seem called for by logic, it hasn't happened, for several reasons:

- First, medicinal reputations of herbs have been kept alive by knowledge that herbs were the original source of many important medicines, such as the heart medicine digitalis derived from the foxglove plant (*Digitalis purpurea*). Also, scientific research on the therapeutic properties of botanicals continues to yield new and useful compounds, such as chymopapain (Chymodiactin), a derivative of the papaya plant, approved in 1982 by FDA for treating certain types of herniated lower back disks. Thus the word "herbs" still wears a kind of halo.
- Second, there are a wide variety of publications—such as "natural" or wild food guides, books on American Indian lore, and modern herb manuals—extolling the virtues of the "healthful herbs."
- Third, there is the attraction that "natural" foods currently hold for those who want their food and drink farther from the test tube and closer to nature.
- And fourth, there has been the search for beverages less burdened with calories or caffeine.

The soaring figures on sales indicate that a great many persons are reaching out to embrace the magic of herbs. They simultaneously satisfy their desire for natural products and for low-calorie, caffeine-free drinks by consuming herbal teas—mint, chamomile, and some 400 other now commercially available combinations of herbs and spices. Given this new trend, it's well to ask, "Are these teas safe?" The Herb Trade Association, which represents over 200 herb growers, believes they are. As Mark Blumenthal, founder of the association, notes, "Many of these teas have been used in cultures around the world with impunity from toxic reactions for thousands of years." And he adds, "I have no question in my experience personally and in my business that the vast majority of herbs are safe in normal amounts."

While many peppermint, rose hip, orange, and others of the more usual herbal teas do offer delicious alternatives to two traditional drinks that contain caffeine—coffee and common tea (*Camellia sinensis*)—we cannot conclude from these facts that all herbal teas are safe, nor that it's safe to consume large amounts of any herbal tea over extended periods. In weighing the safety of this practice, it's very impor-



Fmali v. Heckler (1983)

715 F.2d 1385

FMALI HERB, INC., Plaintiff-Appellant,
v.
Margaret M. HECKLER,* et al., Defendants-Appellees.

No. 82-4604.

**United States Court of Appeals,
Ninth Circuit.**

*Argued and Submitted May 9, 1983.
Decided Sept. 15, 1983.*

Barry Grossman, Edward T. Hand, William F. Baxter, Nancy C. Garrison, Dept. of Justice, Washington, D.C., for defendants-appellees.

William R. Pendergrast, Hamel, Park, McCabe & Saunders, Washington, D.C., J. Bruce McCubbrey, Fitch, Even, Tabin, Flannery & Welsh, San Francisco, Cal., for plaintiff-appellant.

Appeal from the United States District Court for the Northern District of California.

Before PECK,** FLETCHER, and PREGERSON, Circuit Judges.

FLETCHER, Circuit Judge:

1 This case presents a question of first impression arising under section 201(s) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s). The issue is whether the Food and Drug Administration (FDA) has properly interpreted the statute, which provides that the safety of substances added to food may be established by experience based on common use in food prior to 1958. We conclude that, even according the deference due an administrative agency's interpretation of a statute that it is responsible for enforcing, the challenged FDA regulation does not fairly reflect either the language or purpose of the "common use in food" portion of section 201(s). We therefore reverse the district court's declaration that the regulation is valid.

2 * BACKGROUND

3 Section 201(s) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s) (1976), defines a "food additive" as a substance, added to food, that is

4 not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

5 The question whether a substance is a "food additive" is significant because all "food additives" must by law undergo costly pretesting procedures before they may be marketed to the public. See 21 U.S.C. § 348 (1976).

6 In 1974, the FDA promulgated a regulation defining the term "common use in food" for purposes of section 201(s). The regulation states that " '[c]ommon use in food' means a substantial history of consumption of a substance by a significant number of consumers in the United States." 21 C.F.R. § 170.3(f) (1982) (emphasis added). Thus, according to

Item #3

FMALI HERB COMPANY

WILDCRAFT HERBS

831 ALMAR AVE., SANTA CRUZ, CALIFORNIA 95060 U.S.A.
TEL: (408) 423-7913 TELEX: 352-025 CABLE: FMALI SACZ

June 1982

- NEWS RELEASE -

On June 16, 1982 suit was filed in Federal District Court of San Francisco by Attorneys for Fmali Herb Co.,Inc., of Santa Cruz, California against the FDA over the issue of prior use of foods in the United States.

Fmali contends in its suit that herbs found to be safe by common use in foods anywhere in the world prior to 1958 should be available for use in the U.S. The FDA contends such free sale is only allowed when prior use to 1958 is in the U.S.A.

Fmali's position is that so long as proof is documented that herbs were and are used as safe food or tea, then the FDA should not prohibit their sale and distribution as a tea or food. FDA contends that the law implies or states food use in the U.S. Attorneys for Fmali contend there is no basis in law or fact, nor was it intended when Congress passed legislation in 1958. The basic assumption of Fmali's position is that people's metabolism is the same all over the world. If an herb is proven safe for Chinese and Englishmen, then it is safe for Americans so long as it can be documented.

The issue of proof of safety and regulatory labeling of such herbal food or teas is not an issue in the case. FDA's regulatory function of reviewing use and safety data is not contested. Fmali wishes to clarify the regulation by allowing the Court to rule that FDA's interpretation is discriminatory and with no basis of law by limiting its interpretation to prior use in the U.S.A.

For further information, you may contact the following:

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* * * * *

2022 NutraIngredients-USA article on Fmali case

NUTRA ingredients-usa.com

Fmali v Heckler: The landmark herb case that changed the industry

By Stephen Daniells
02-Mar-2022 - Last updated on 02-Mar-2022 at 16:09 GMT

Schisandra chinensis or five-flavor berry on a branch. The berries possess all five basic flavors in Chinese herbal medicine: salty, sweet, sour, pungent (spicy), and bitter. Image © Geshas / Getty Images

The Next Food Additive Theory: Black Currant (1988)

791 F.Supp. 751 (C.D.Ill. 1991)

UNITED STATES of America, Plaintiff,

v.

TWO PLASTIC DRUMS, MORE OR LESS OF AN ARTICLE OF FOOD, LABELED IN PART: VIPONTE LTD. BLACK CURRANT OIL BATCH NO. BOOSF 039, Etc., Defendants.

Claim of TRACO LABS, INC., Claimant.

No. 88-CV-2398.

United States District Court, C.D. Illinois.

Nov. 27, 1991

David Hoff, Asst. U.S. Atty., Frances Hulin, Asst. U.S. Atty., Danville, Ill., for plaintiff.

Robert Ullman, Steven Shapiro, Bass & Ullman, New York City, for defendant.

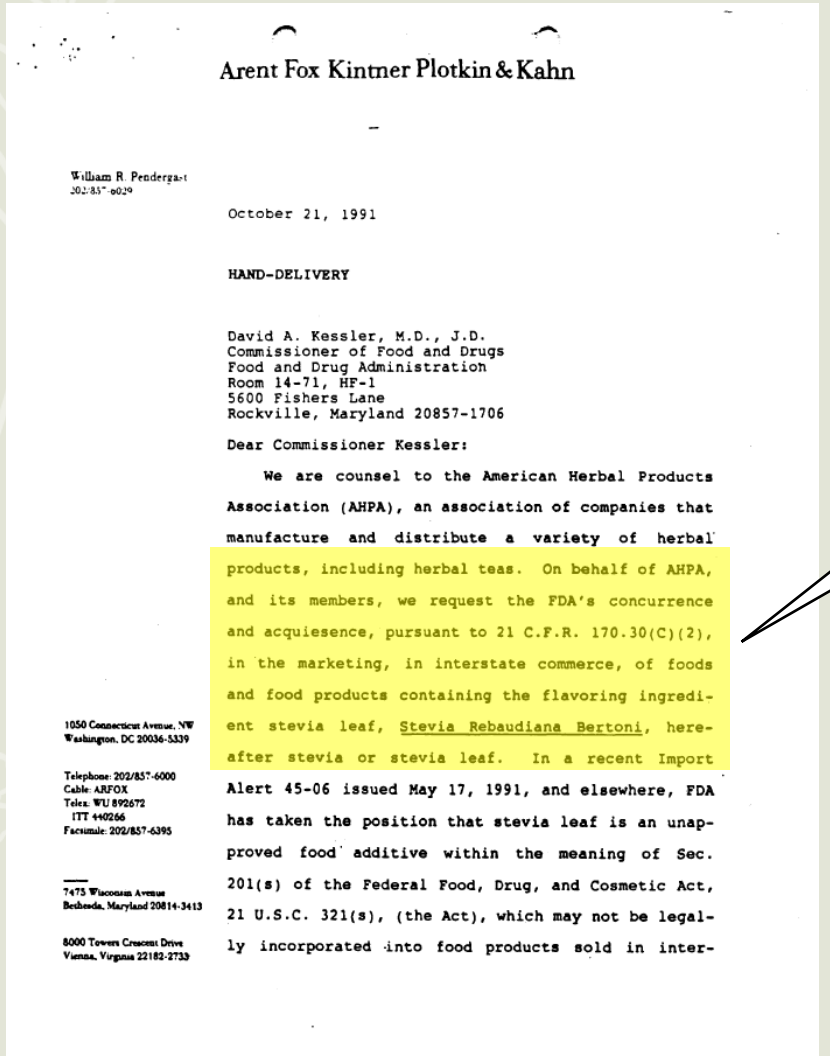
ORDER ON TRACO'S MOTION FOR SUMMARY JUDGMENT

BAKER, District Judge.

This is an *in rem* seizure action under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-394 (1972 & Supp.) (the "Act"). The plaintiff, the United States of America, through the Food and Drug Administration, seeks to condemn and destroy two drums of black currant oil ("BCO"). BCO is extracted from the seeds of the black currant berry and is marketed as a dietary supplement. [1] Its proponents claim that it provides health benefits because of its unique fatty-acid structures. The claimant, Traco Labs, Inc., asserts that the drums belong to it and that they cannot be condemned. Traco has moved for summary judgment pursuant to Fed.R.Civ.P. 56 and the FDA objects.

"The plaintiff, the United States of America, through the Food and Drug Administration, **seeks to condemn and destroy two drums of black currant oil**…"

The Next, Next Food Additive Theory: Stevia (1991)



Arent Fox Kintner Plotkin & Kahn

William R. Pendergast
202/857-6029

October 21, 1991

HAND-DELIVERY

David A. Kessler, M.D., J.D.
Commissioner of Food and Drugs
Food and Drug Administration
Room 14-71, HF-1
5600 Fishers Lane
Rockville, Maryland 20857-1706

Dear Commissioner Kessler:

We are counsel to the American Herbal Products Association (AHPA), an association of companies that manufacture and distribute a variety of herbal products, including herbal teas. On behalf of AHPA, and its members, we request the FDA's concurrence and acquiesence, pursuant to 21 C.F.R. 170.30(C)(2), in the marketing, in interstate commerce, of foods and food products containing the flavoring ingredient stevia leaf, Stevia Rebaudiana Bertoni, here-after stevia or stevia leaf. In a recent Import Alert 45-06 issued May 17, 1991, and elsewhere, FDA has taken the position that stevia leaf is an unapproved food additive within the meaning of Sec. 201(s) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(s), (the Act), which may not be legally incorporated into food products sold in inter-

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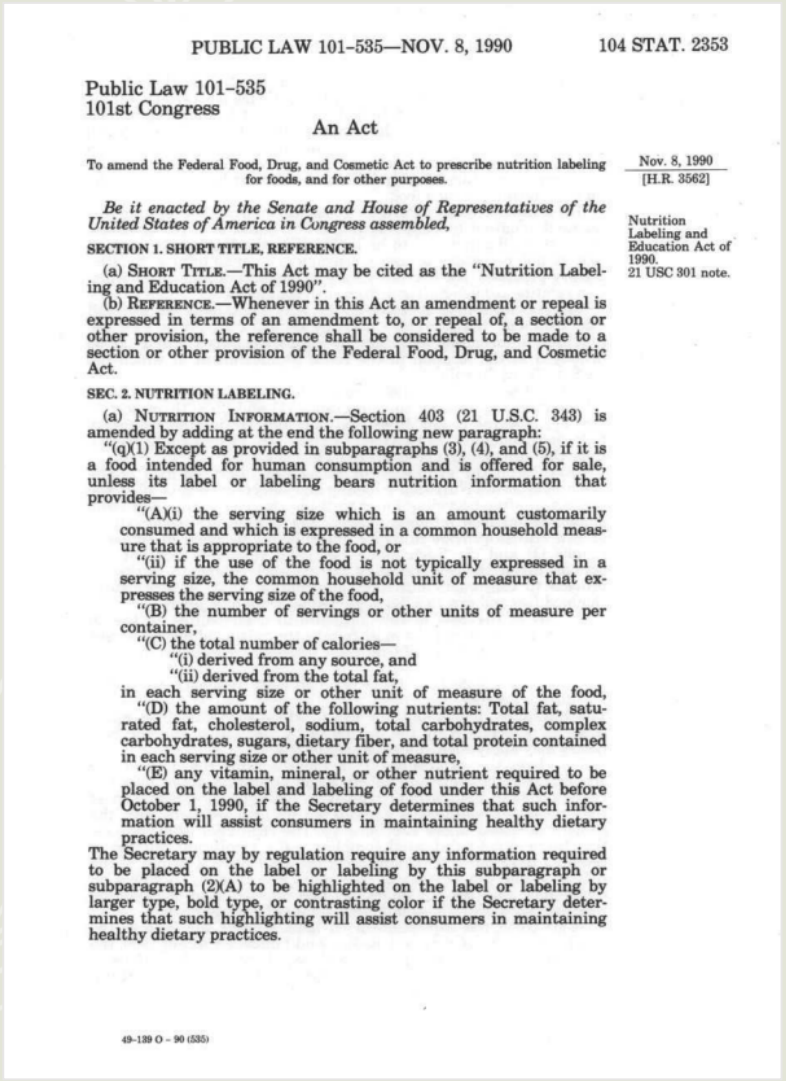
On behalf of AHPA, and its members, we request the FDA's concurrence and acquiescence, pursuant to 21 C.F.R. 170.30(C)(2), in the marketing, in the interstate commerce, of foods and food products containing the flavoring ingredient stevia leaf, Stevia Rebaudiana Bertoni, here-after stevia or stevia leaf.

Nutrition Labeling and Education Act (NLEA) of 1990



PUBLIC LAW 101-535—NOV. 8, 1990 104 STAT. 2353

Public Law 101-535
101st Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to prescribe nutrition labeling for foods, and for other purposes.

Nov. 8, 1990
[H.R. 3562]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Nutrition Labeling and Education Act of 1990.
21 USC 301 note.

SECTION 1. SHORT TITLE, REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Nutrition Labeling and Education Act of 1990".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. NUTRITION LABELING.

(a) NUTRITION INFORMATION.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following new paragraph:

"(q)(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

"(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

"(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

"(B) the number of servings or other units of measure per container,

"(C) the total number of calories—

"(i) derived from any source, and

"(ii) derived from the total fat,

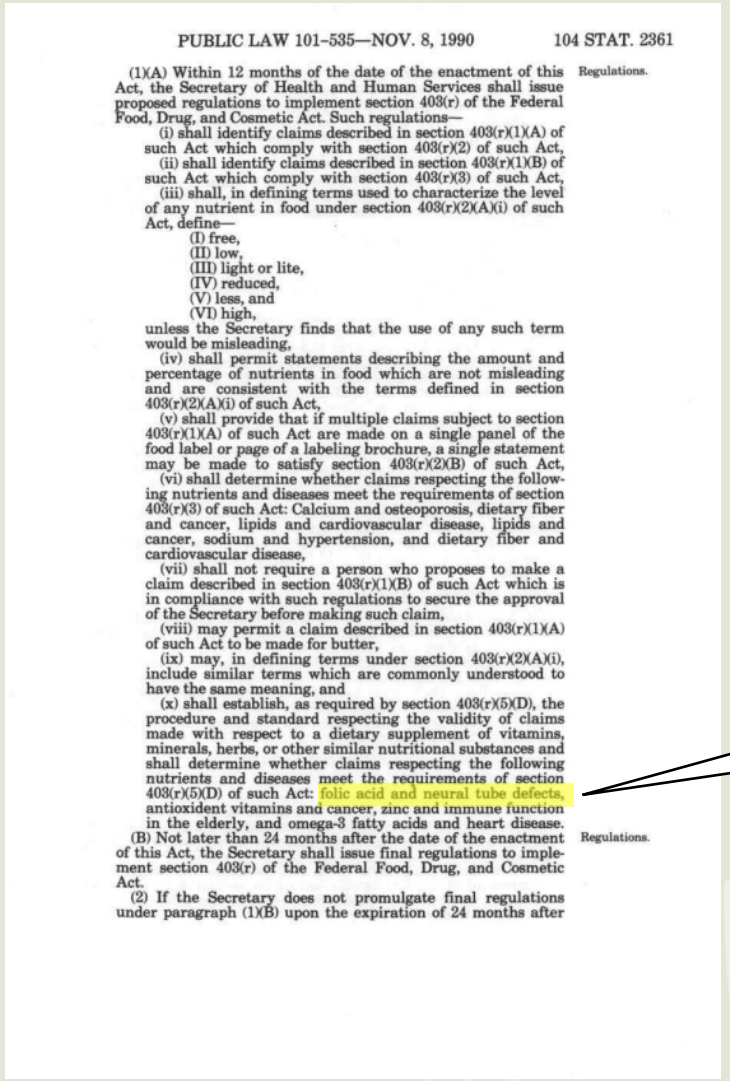
in each serving size or other unit of measure of the food,

"(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

"(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

49-139 O - 90 (535)



PUBLIC LAW 101-535—NOV. 8, 1990 104 STAT. 2361

(1)(A) Within 12 months of the date of the enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act. Such regulations— Regulations.

(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

(I) free,
(II) low,
(III) light or lite,
(IV) reduced,
(V) less, and
(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

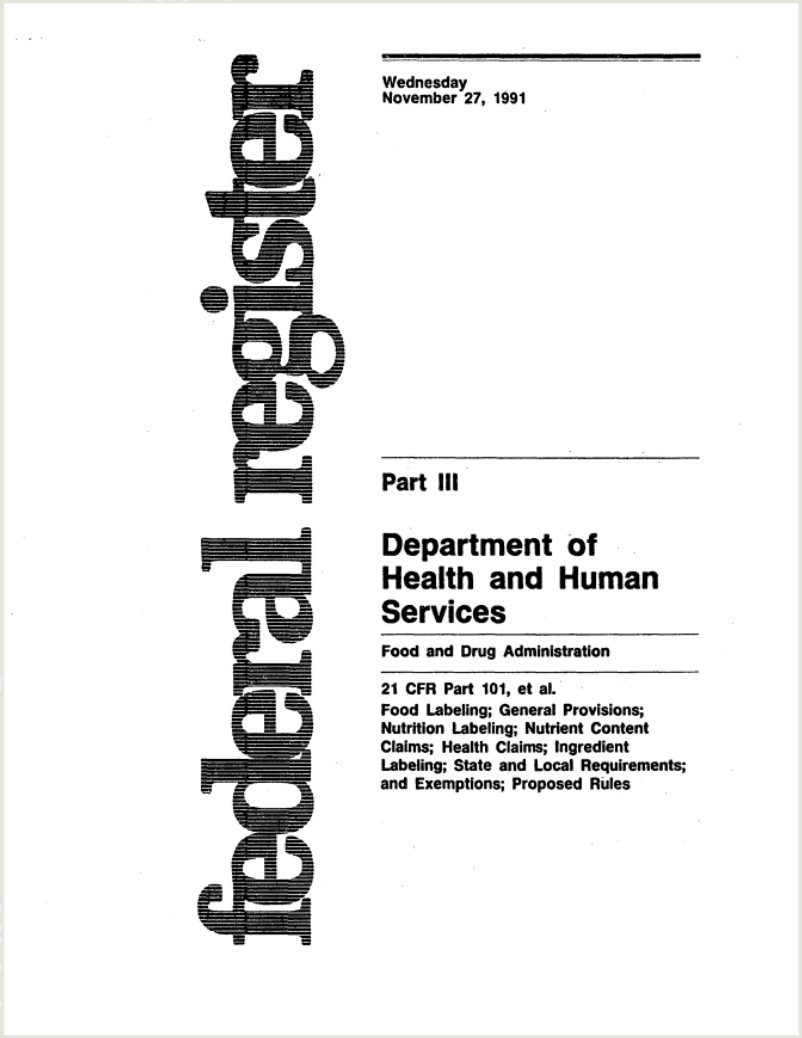
(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxident vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act. Regulations.

(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after

…folic acid and neural tube defects…

FDA's Proposed Rules for Health Claims Under NLEA (1991)



federal register

Wednesday
November 27, 1991

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101, et al.
Food Labeling; General Provisions; Nutrition Labeling; Nutrient Content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Proposed Rules

Federal Register / Vol. 56, No. 229 / Wednesday, November 27, 1991 / Proposed Rules 60545

an amount that exceeds the disqualifying level. FDA is not proposing to make an exception for whole milk because low fat milk and skim milk could bear such a claim. Thus, the agency believes that there is no basis to make a finding that permitting such a claim on whole milk would assist consumers in maintaining health dietary practices. The agency requests comments on the appropriateness of its approach to this issue. It has been suggested that the agency should consider the net public health benefit in deciding whether to permit a claim on a food that contains a nutrient at a level that exceeds the disqualifying level (e.g., an osteoporosis claim on a food high in fat). This suggestion is that there are advantages in allowing such claims with full and prominent disclosure regarding other nutrients, similar to the requirements for nutrient claims, because the public health gain from consuming the nutrient that is the subject of the health claim would outweigh the risks from consuming the nutrient that would otherwise disqualify the food. A benefit would derive from consuming the nutrient that is the subject of the claim, and a person could balance his or her intake of the disqualifying nutrient by other food selections as part of a total diet. FDA requests comments on this and other approaches in implementing section 403(r)(3)(A)(ii) of the act.

FDA requests comments, including data or other information, on the proposed disqualification levels. If the agency is persuaded by comments that other disqualifying levels, or that modifications in the proposed disqualifying levels, would be more appropriate, FDA will consider making any appropriate changes in the final rule that is based on this proposal.

The agency recognizes that dietary supplements are not subject to the provisions of section 403(r)(3) of the act. However, as explained previously, FDA has tentatively determined that supplements are appropriately subject to the same rules as conventional foods. As a practical matter, however, FDA doubts that disqualifying levels will have any significant impact on supplements because supplements are formulated products that are being promoted as healthful. It would not be logical for such products to be formulated with significant levels of nutrients with known adverse effects.

B. Preliminary Requirements

Congress and FDA, in proposed § 101.14(a)(2), have broadly defined the substances that may be the subject of a health claim. Consequently, FDA anticipates receiving a wide range of petitions for health claims. However, based on the act as a whole, FDA believes that there are certain criteria that must be met before a substance would qualify as the subject of a health claim. The agency is proposing these criteria in § 101.14(b). They reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring the safety of the food supply, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA is proposing not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements in proposed § 101.14(b) are met.

1. Effect on General U.S. Population

Section 403(r)(3)(b)(iii) of the act requires that a health claim be stated in a manner "* * * so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet." FDA believes that, for this requirement to be satisfied, the general U.S. population or some identified subgroup must be at risk with respect to the particular diet-related diease or condition, or, if that is not the case, the proponent of the health claim and any claim approved by FDA otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet. This would permit claims to be evaluated even if no showing was made that any particular population group is currently at risk, but it would require that such information be provided as part of any resulting health claim. In addition, the label or labeling would be required to include any potential risks posed by the nutrient for which the claim is made.

2. Components in Food Within Context of Daily Diet

As stated above, Congress and FDA have provided for a wide variety of food components as potential subjects of health claims. These components range from desirable components, such as essential nutrients, to components whose intake should be limited, such as saturated fat, and even to components that have traditionally served primarily as sources of flavor or aroma, such as herbs.

However, the agency does not believe that Congress intended that everything that can be formulated into a form in which it could be consumed enterally should qualify for health claims. To the contrary, a firm could not add a drug to a food to justify a health claim (e.g., addition of aspirin or an herb whose only known use is for medicinal effects such as belladonna, rauwolfia, or yellow dock). Such addition would make the food a drug within the meaning of section 201(g) of the act. Any substance that is to be the subject of a claim must meet the definition of a "food" under section 201(f) of the act. Consequently, the agency is proposing § 101.14(b)(2) and (b)(3) to assure that claims are made only for substances that are foods.

With respect to what constitutes food, FDA advises that section 201(f) of the act states that the term "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article." This statutory definition has been interpreted by case law (*Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)) to include "common sense foods," that is, articles used primarily for taste, aroma, or nutritive value, as well as components of food, both inherent and added.

Consistent with the statute and applicable case law, FDA is proposing in § 101.14(b)(3)(i) that a substance that is the subject of a suggested claim that explains the advantages of consuming the substance at other than decreased levels must contribute taste, aroma, or nutritional value to a food, or serve one or more of the technical effects listed in 21 CFR 170.3(o) (e.g., nutrient supplement). In addition, Congress explicitly directed in section 403(r)(3)(B)(iii) of the act that regulations permitting health claims allow the public to comprehend the significance of the health benefit within the context of the total daily diet so that consumers may modify their diets to achieve public health goals. Obviously a substance must be a food for it to have any significance in the diet.

For consumption of a substance to have significance within the context of the daily diet, FDA is also proposing in § 101.14(b)(3)(i) that the substance must retain its food attributes at the levels that are necessary to justify the claim. For example, if the substance is a vitamin that must be present at a therapeutic level for a health benefit to occur, the supplement would not qualify for a health claim under this proposal. A therapeutic level of a vitamin would be far above that level that is normally characteristic of food, and, consequently, the vitamin would not retain its food attributes. However, FDA is not proposing a specific definition in the general provisions of this proposal

"…the agency does not believe that Congress intended that everything that can be formulated into a form in which it could be consumed enterally should qualify for health claims. To the contrary, a firm could not add a drug to a food to justify a health claim (e.g., addition of aspirin or an herb whose only known use is for medicinal effects **such as belladonna, rauwolfia, or yellow dock**). Such addition would make the food a drug within the meaning of section 201(g) of the act. Any substance that is to be the subject of a claim must meet the definition of a "food" under section 201(f) of the act."

FDA's Proposed Rules for Health Claims Under NLEA (1991)

60610 Federal Register / Vol. 56, No. 229 / Wednesday, November 27, 1991 / Proposed Rules

21 CFR Part 101

[Docket No. 91N-0100]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Folic Acid and Neural Tube Defects

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize the use on the label and labeling of foods, including dietary supplements, of health claims relating to an association between folic acid and reduction in risk of neural tube defects. FDA has reviewed the scientific data in conformity with the requirements of the Nutrition Labeling and Education Act (the 1990 amendments) and has tentatively concluded that there is not a sufficient basis to support the use of health claims relating to this topic. FDA also reviewed recently published results of a large intervention trial of effects of supplements containing very high levels of folic acid in women who, because of histories of neural tube defect-complicated pregnancies, were at high risk of recurrences of these specific birth defects in subsequent pregnancies. Currently there is not significant agreement among qualified experts that intakes of folic acid lower than those studied in this intervention trial will have the same effect as that observed with very high intakes.

Additionally, at this time, there is no significant agreement among qualified experts that folic acid supplementation of women at much lower risk of occurrence of neural tube defect-affected pregnancies will reduce the risk of such a complication. However, the results of the recently published intervention trial are causing some qualified experts to reevaluate the preexisting evidence. FDA will consider all developments in this regard and reflect such developments in any final rule that it issues. FDA has tentatively concluded that claims on foods, including dietary supplements, relating to folic acid and reduction in risk of neural tube birth defects are not justified.

DATES: Written comments by (January 27, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-6067.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 1990 Amendments

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary), and FDA by delegation, to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule to establish general requirements pertaining to the use of health claims on food labels and in labeling that characterize the relationship of nutrients, including vitamins and minerals, herbs, or other nutritional substances (referred to generally as "substances") to a disease or health-related condition. In this document entitled "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule (the companion document), "FDA has tentatively concluded that such claims would only be justified for substances in dietary supplements as well as in conventional foods if the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles) supports a claim; and if there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims about such support.

The 1990 amendments also require (section 3 (b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)), that within 12 months of enactment, the Secretary issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including folic acid and neural tube defects, meet the requirements of the act. In this document, the agency considers whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between folic acid and neural tube defects would be justified under the standard proposed in the companion document.

FDA has followed the general concepts and criteria proposed in the companion document in considering whether to propose to authorize the use on the labels and labeling of food of health claims for folic acid and neural tube defects. In the companion document, FDA has proposed that, in evaluating whether support exists for a health claim, it will consider the levels and safety of a nutrient within the context of its use in the daily diet. Before a health claim for a particular nutrient will be authorized, it is necessary that the nutrient be safe and lawful for use in food at the level found to have an effect on a disease or health condition.

The topic of folic acid and neural tube defects involves a substance which has recognized uses both as a component of food and of drugs. The agency has looked at all data relevant to this topic whether the data involved tests at dietary levels or at therapeutic levels. The agency thought this necessary to ensure the completeness of its review. However, the agency emphasizes that this proposal is only about whether a claim has been justified for folic acid on food. A component of food must be safe in the context of the daily diet. On the other hand, drugs may be used even if they present questions of safety to the general population, and even to the population being treated, on the basis that there is a benefit from its use that outweighs the potential risk.

B. Folic Acid and Neural Tube Defects: Public Health Aspects

Congenital malformations are structural abnormalities that are present at birth. Several specific malformations of the central nervous system (CNS) are referred to as "neural tube defects" because the brain and spinal cord develop within the neural tube. The neural tube forms early in fetal life, between the 18th and 20th days of pregnancy, and closes between the 24th and 27th days of pregnancy. Neural tube defects include a wide range of abnormalities of the CNS. They may be isolated malformations or may occur in association with other nonneural congenital malformations.

60624 Federal Register / Vol. 56, No. 229 / Wednesday, November 27, 1991 / Proposed Rules

SW., Washington, DC, and Harold A. Kaminetzky, MD, FACOG, Director of Practice Activities, memo to file, April 4, 1991.

30. Spina Bifida Association of America, 1700 Rockville Pike, Rockville, MD, memo to file, June 27, 1991.

31. Scott, William, Chairman, Public Affairs Committee, Teratology Society, 9650 Rockville Pike, Bethesda, MD, memo to file, April 7, 1991.

32. Wald, N. J., "Neural Tube Defects and Vitamins: The Need for a Randomized Clinical Trial," *British Journal of Obstetrics and Gynecology*, 91:516-523, 1984.

33. Vergel, R. G., L. R. Sanchez, B. L. Heredero, P. L. Rodriquez, and A. J. Martinez, "Primary Prevention of Neural Tube Defects with Folic Acid Supplementation: Cuban Experience," *Prenatal Diagnosis*, 10:149-152, 1990.

34. Mills, J. L., G. G. Rhoads, J. L. Simpson, G. C. Cunningham, M. R. Conley, M. R. Lassman, M. E. Walden, R. Depp, and H. J. Hoffman, "The Absence of a Relation Between the Periconceptional Use of Vitamins and Neural-tube Defects," *New England Journal of Medicine*, 321:430-435, 1989.

35. Bower, C., and F. J. Stanley, "Dietary Folate as a Risk Factor for Neural-tube Defects: Evidence from a Case-control Study in Western Australia," *Medical Journal of Australia*, 150:613-619, 1989.

36. Mulinare, J., J. F. Cordero, J. D. Erickson, and R. J. Berry, "Periconceptional Use of Multivitamins and the Occurrence of Neural Tube Defects," *Journal of the American Medical Association*, 260:3141-3145, 1988.

37. Milunsky, A., H. Jick, S. S. Jick, C. L. Bruell, D. S. MacLaughlin, K. J. Rothman, and W. Willett, "Multivitamin/Folic Acid Supplementation in Early Pregnancy Reduces the Prevalence of Neural Tube Defects," *Journal of the American Medical Association*, 262:2847-2852, 1989.

38. Mills, J. L., G. G. Rhoads, J. L. Simpson, and G. C. Cunningham, letter to the editor, *Journal of the American Medical Association*, 263:2747-2748, 1990.

39. Shapiro, S., A. A. Mitchell, M. M. Werler, letter to the editor, *Journal of the American Medical Association*, 263:2748, 1990.

40. Milunsky, A., H. Jick, S. S. Jick, K. J. Rothman, W. Willett, "In Reply," *Journal of the American Medical Association*, 263:2748-2749.

41. Seller, M. J., and N. C. Nevin, letter to the editor, *Journal of the American Medical Association*, 263:2749, 1990.

42. Halstead, C. H., "Periconceptional Use of Multivitamins and the Prevalence of Neural Tube Defects," letter to the editor, *New England Journal of Medicine*, 322:1082, 1990.

43. Milunsky, A., H. Jick, S. S. Jick, and W. Willett, letter to the editor, *New England Journal of Medicine*, 322:1082-1083, 1990.

44. Mulinare, J., J. F. Cordero, J. D. Erickson, and R. J. Berry, letter to the editor, *New England Journal of Medicine*, 322:1083, 1990.

45. Mills, J. L., G. G. Rhoads, H. T. Hoffman, J. L. Simpson, G. C. Cunningham, and M. R. Lassman, letter to the editor, *New England Journal of Medicine*, 322:1083-1084, 1990.

46. Mulinare, J., J. F. Cordero, J. D. Erickson, and R. J. Berry, letter to the editor, *New England Journal of Medicine*, 322:1085, 1990.

47. Seller M. J., and N. C. Nevin, "Periconceptional Vitamin Supplementation and the Prevention of Neural Tube Defects in Southeast England and Northern Ireland," *Journal of Medical Genetics*, 21:325-330, 1984.

48. Molloy, A. M., P. Kirke, I. Hillary, D. G. Weir, and J. M. Scott, "Maternal Serum Folate and Vitamin B_{12} Concentrations in Pregnancies Associated With Neural Tube Defects," *Archives of Disease in Childhood*, 60:660-665, 1985.

49. Yates, J. R. W., M. A. Ferguson-Smith, A. Shenkin, R. Guzman-Rodriquez, M. White, and B. J. Clark, "Is Disordered Folate Metabolism the Basis for the Genetic Predisposition to Neural Tube Defects?", *Clinical Genetics*, 31:279-287, 1987.

50. Mills, J. L., J. Tuomilehto, K. F. Yu, W. Rundle, W. Bluner, P. Koskella, N. Colman, M. Forman, L. Toivanen, and G. G. Rhoads, "Maternal Vitamin Levels During Pregnancies Producing Infants with Neural tube Defects," *Pediatric Research*, 29 (No. 4, Part 2:71A), 1991.

51. Kulter H., and J. Warkeny, "Experimental Production of Congenital Malformations in Mammals by Metabolic Procedure," *Physiological Reviews*, 39:69-115, 1959.

52. Nelson, M. M., H. V. Wright, C. W. Asling, H. M. Evans, "Multiple Congenital Abnormalities Resulting from Transitory Deficiency of Pteroylglutamic Acid During Gestation in the Rat," *Journal of Nutrition*, 56:349-309, 1955.

53. Embury, S., M. J. Seller, M. Adinolfi, and P. E. Polani, "Neural Tube Defects in Curly-tail Mice. 1. Incidence and Expression," *Proceedings of the Royal Society of London. Series B: Biological Sciences*, 206:85-94, 1979.

54. Seller, M. J., and M. Adinolfi, "The Curly-tail Mouse: An Experimental Model For Human Neural Tube Defects," *Life Sciences*, 29:1667-1655, 1981.

55. Graham J. M., and V. H. Form, "Heat- and Alcohol-induced Neural Tube Defects: Interactions with Folate in a Golden Hamster Model," *Pediatric Research*, 19 (2) 247-251, 1985.

56. Trotz, M., C. Wegner, and H. Nau, "Valproic Acid-induced Neural Tube Defects: Reduction by Folinic Acid in the Mouse," *Life Sciences*, 41:103-110, 1987.

57. Wegner, C. H. R, and N. Nau, "Valproic Acid-induced Neural Tube Defects: Disturbance of the Folate Metabolism in Day 9 Mouse Embryo," *Teratology*, 39:488, 1989.

58. Ghishan, F. K., H. M. Said, R. C. Wilson, J. E. Morrell, and H. L. Greene, "Intestinal Transport of Zinc and Folic Acid: A Mutual Inhibitory Effect," *American Journal of Clinical Nutrition*, 43:258-262, 1986.

59. Simmer, K., C. James, and R. P. H. Thompson, "Are Iron-folate Supplements Harmful?", *American Journal of Clinical Nutrition*, 45:122-125, 1987.

60. Laurence K. M., "Dietary Approaches to the Prevention of Neural Tube Defects," *Nutrition and Health*, 2:181-189, 1983.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding paragraph (c) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(c) Folic acid and neural tube defects (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27167 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

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(c) Folic acid and neural tube defects (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

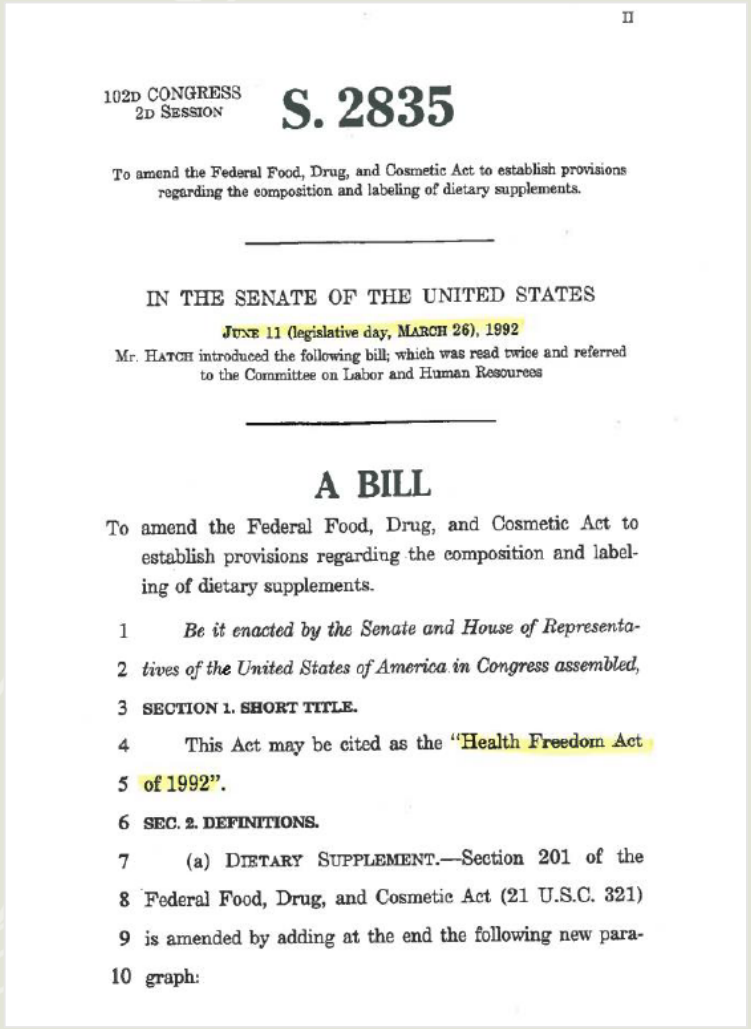
Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27167 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

Health Freedom Act (1992)



II

102D CONGRESS
2D SESSION

S. 2835

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

IN THE SENATE OF THE UNITED STATES

JUNE 11 (legislative day, MARCH 26), 1992

Mr. HATCH introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

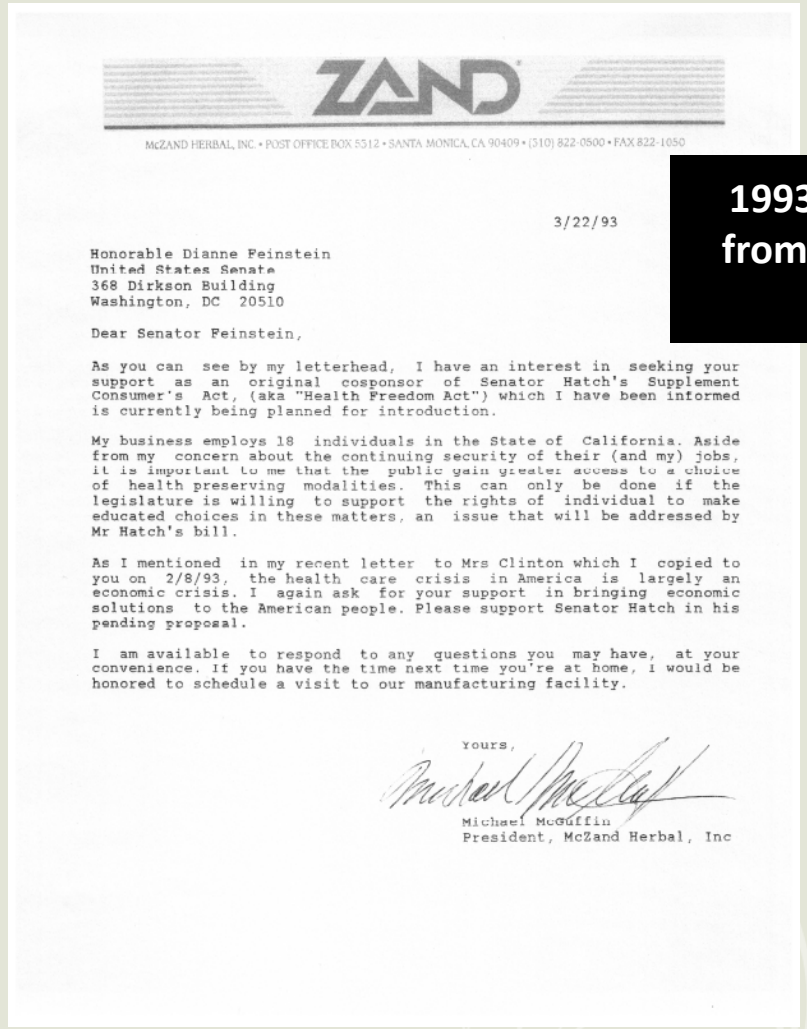
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Health Freedom Act of 1992".

SEC. 2. DEFINITIONS.

(a) DIETARY SUPPLEMENT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following new paragraph:



ZAND

McZAND HERBAL, INC. • POST OFFICE BOX 5512 • SANTA MONICA, CA 90409 • (310) 822-0500 • FAX 822-1050

3/22/93

Honorable Dianne Feinstein
United States Senate
368 Dirkson Building
Washington, DC 20510

Dear Senator Feinstein,

As you can see by my letterhead, I have an interest in seeking your support as an original cosponsor of Senator Hatch's Supplement Consumer's Act, (aka "Health Freedom Act") which I have been informed is currently being planned for introduction.

My business employs 18 individuals in the State of California. Aside from my concern about the continuing security of their (and my) jobs, it is important to me that the public gain greater access to a choice of health preserving modalities. This can only be done if the legislature is willing to support the rights of individual to make educated choices in these matters, an issue that will be addressed by Mr Hatch's bill.

As I mentioned in my recent letter to Mrs Clinton which I copied to you on 2/8/93, the health care crisis in America is largely an economic crisis. I again ask for your support in bringing economic solutions to the American people. Please support Senator Hatch in his pending proposal.

I am available to respond to any questions you may have, at your convenience. If you have the time next time you're at home, I would be honored to schedule a visit to our manufacturing facility.

Yours,

Michael McGuffin
President, McZand Herbal, Inc

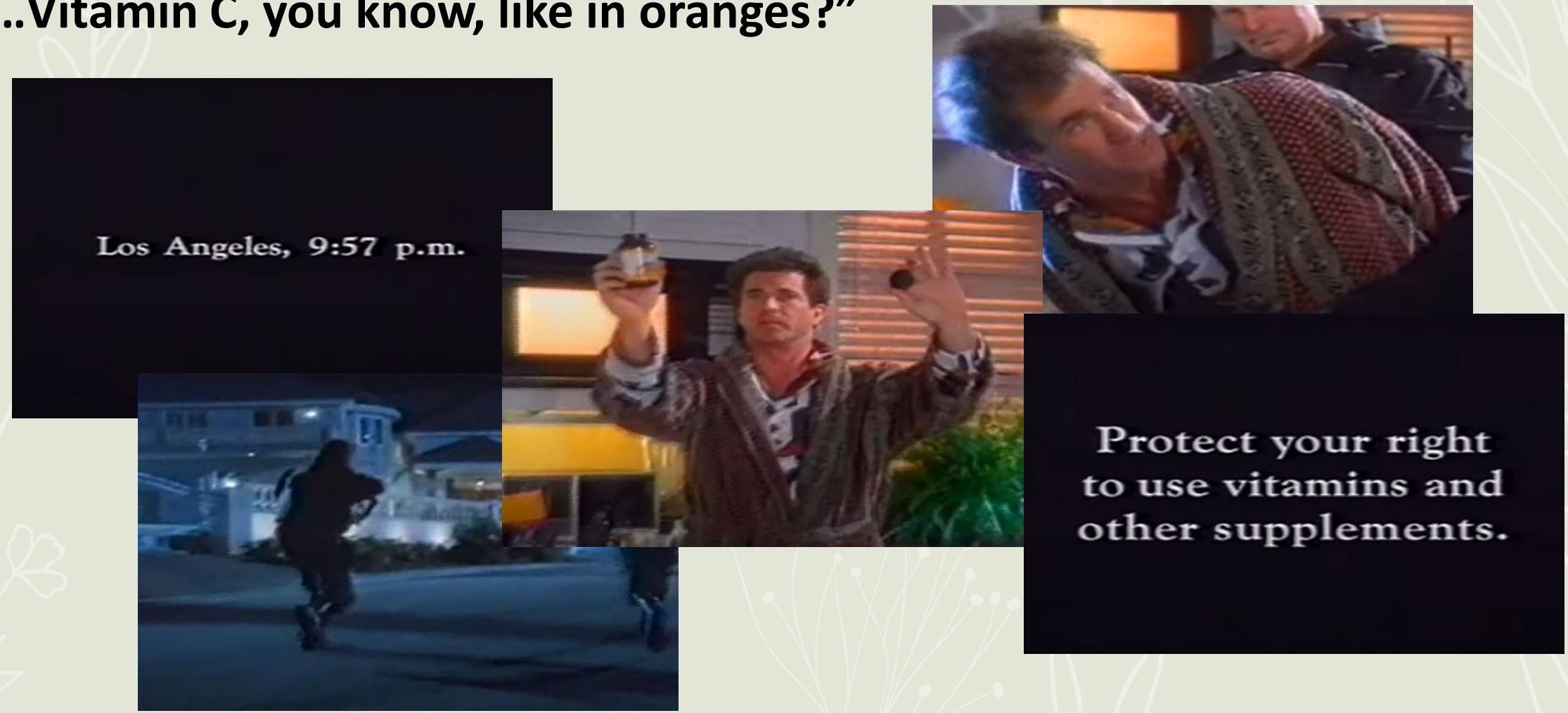
1993 letter to Senator Dianne Feinstein from Michael McGuffin seeking support for Health Freedom Act

“Black Out” Days

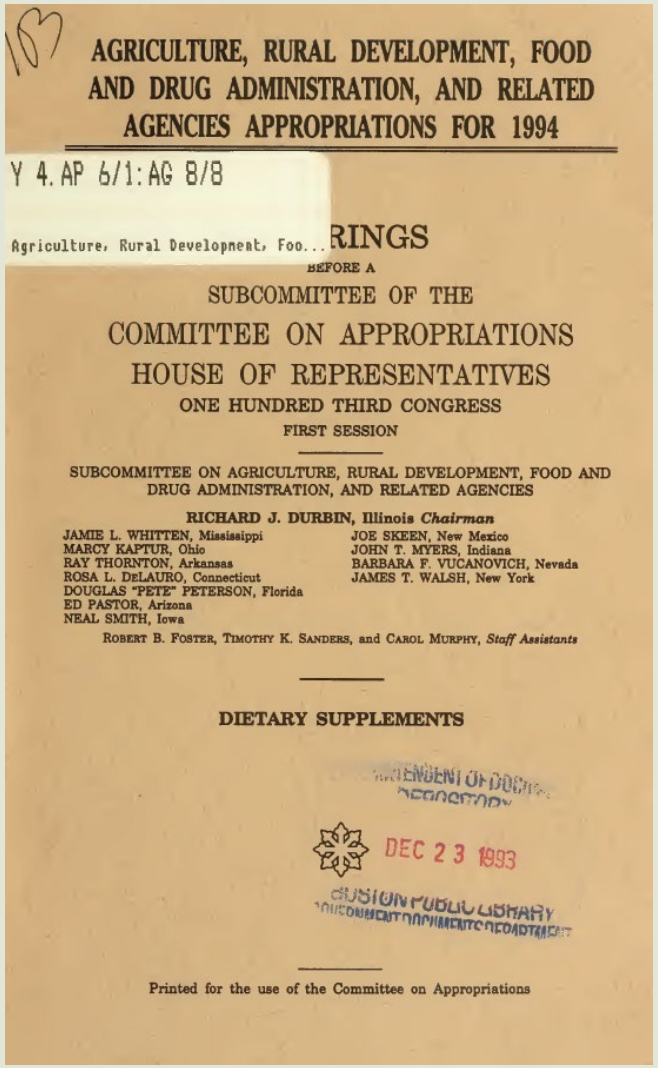
Bill Crawford, today director of retail publishing programs at New Hope Natural Media, was working at a health-food store before DHSEA was passed.

“I vividly recall our putting on a ‘black out’ day. We got black mesh fabric and covered every product that would not be available for sale if DSHEA did not pass. It was nearly our entire supplement section! Products were available for sale but our staff was telling people why we had this restrictive covering […] and signage […] as well. Tables and chairs were set up for any customers who wanted to write a letter to Congress telling them how important access to dietary supplements was to them.”

“It’s only vitamins!
…Vitamin C, you know, like in oranges?”



House Hearing on Dietary Supplements (1993)



AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1994

RINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

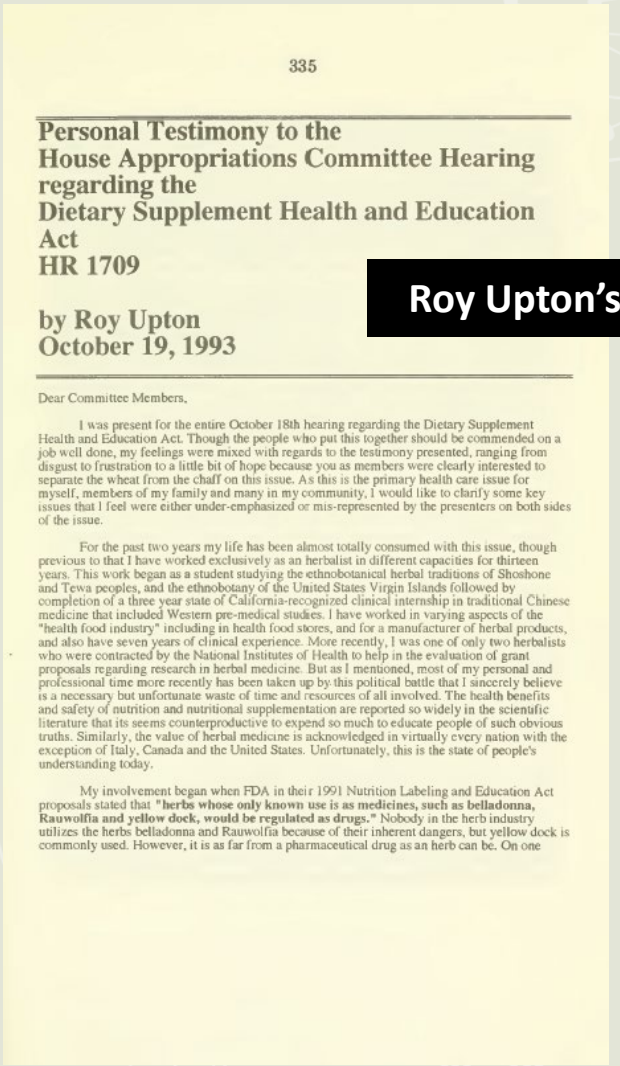
RICHARD J. DURBIN, Illinois *Chairman*

JAMIE L. WHITTEN, Mississippi
MARCY KAPTUR, Ohio
RAY THORNTON, Arkansas
ROSA L. DeLAURO, Connecticut
DOUGLAS "PETE" PETERSON, Florida
ED PASTOR, Arizona
NEAL SMITH, Iowa
JOE SKEEN, New Mexico
JOHN T. MYERS, Indiana
BARBARA F. VUCANOVICH, Nevada
JAMES T. WALSH, New York

ROBERT B. FOSTER, TIMOTHY K. SANDERS, and CAROL MURPHY, *Staff Assistants*

DIETARY SUPPLEMENTS

Printed for the use of the Committee on Appropriations



Personal Testimony to the
House Appropriations Committee Hearing
regarding the
Dietary Supplement Health and Education Act
HR 1709

by Roy Upton
October 19, 1993

Roy Upton's testimony

Dear Committee Members,

I was present for the entire October 18th hearing regarding the Dietary Supplement Health and Education Act. Though the people who put this together should be commended on a job well done, my feelings were mixed with regards to the testimony presented, ranging from disgust to frustration to a little bit of hope because you as members were clearly interested to separate the wheat from the chaff on this issue. As this is the primary health care issue for myself, members of my family and many in my community, I would like to clarify some key issues that I feel were either under-emphasized or mis-represented by the presenters on both sides of the issue.

For the past two years my life has been almost totally consumed with this issue, though previous to that I have worked exclusively as an herbalist in different capacities for thirteen years. This work began as a student studying the ethnobotanical herbal traditions of Shoshone and Tewa peoples, and the ethnobotany of the United States Virgin Islands followed by completion of a three year state of California-recognized clinical internship in traditional Chinese medicine that included Western pre-medical studies. I have worked in varying aspects of the "health food industry" including in health food stores, and for a manufacturer of herbal products, and also have seven years of clinical experience. More recently, I was one of only two herbalists who were contracted by the National Institutes of Health to help in the evaluation of grant proposals regarding research in herbal medicine. But as I mentioned, most of my personal and professional time more recently has been taken up by this political battle that I sincerely believe is a necessary but unfortunate waste of time and resources of all involved. The health benefits and safety of nutrition and nutritional supplementation are reported so widely in the scientific literature that its seems counterproductive to expend so much to educate people of such obvious truths. Similarly, the value of herbal medicine is acknowledged in virtually every nation with the exception of Italy, Canada and the United States. Unfortunately, this is the state of people's understanding today.

My involvement began when FDA in their 1991 Nutrition Labeling and Education Act proposals stated that **"herbs whose only known use is as medicines, such as belladonna, Rauwolfia and yellow dock, would be regulated as drugs."** Nobody in the herb industry utilizes the herbs belladonna and Rauwolfia because of their inherent dangers, but yellow dock is commonly used. However, it is as far from a pharmaceutical drug as an herb can be. On one

Dietary Supplement Health and Education Act of 1994

One Hundred Third Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday,
the twenty-fifth day of January, one thousand nine hundred and ninety-four

An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

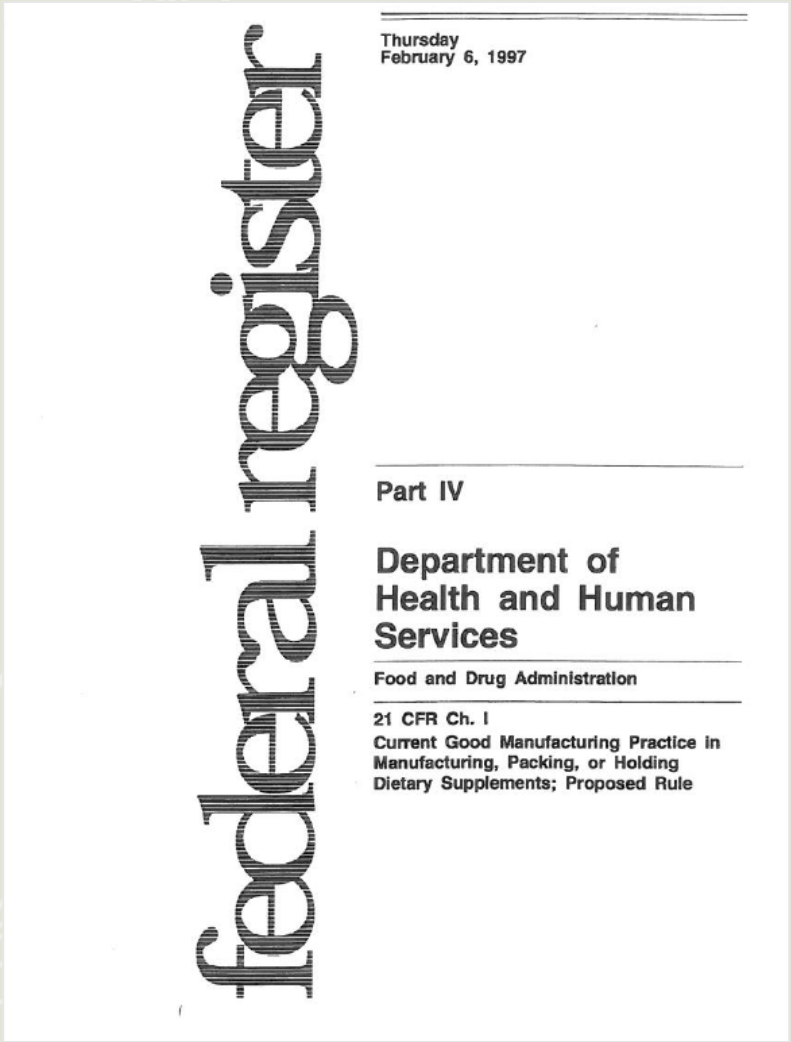
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Dietary Supplement Health and Education Act of 1994".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

cGMP (1997)



federal register

Thursday
February 6, 1997

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Ch. I

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rule

5700 Federal Register / Vol. 62, No. 25 / Thursday, February 6, 1997 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 96N–0417]

RIN 0910–AA59

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering whether to institute rulemaking to develop current good manufacturing practice (CGMP) regulations for dietary supplements and dietary supplement ingredients. FDA solicits comments on whether it should do so, and if it should, what constitutes CGMP for these products. In issuing this notice, FDA is responding to the section of the Federal Food, Drug, and Cosmetic Act (the act) that provides that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practice for dietary supplements and to a submission from representatives of the dietary supplement industry asking FDA to consider a framework that the industry had developed as a basis for CGMP regulations. FDA is publishing the industry submission and is asking for public comment on the framework that the submission presents. In addition, FDA is requesting comment on a number of other related issues.

DATES: Written comments by May 7, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 1994, the Dietary Supplement Health and Education Act (the DSHEA) (Pub. L. 103–417) was signed into law. The DSHEA, among other things, amended the act by adding section 402(g) (21 U.S.C. 342(g)), which provides, in part, that:

The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

While section 402(g) of the act does not require that the Secretary (and by delegation, FDA) adopt regulations that prescribe CGMP, a significant segment of the dietary supplement industry has told the agency that such regulations would be helpful for ensuring that dietary supplements are safe for their intended use.

On November 20, 1995, representatives of the dietary supplement industry submitted to FDA a suggested outline for the development of CGMP regulations for dietary supplements. FDA evaluated the outline and determined that it provided an extremely useful starting point should FDA decide to proceed to rulemaking to adopt such regulations. However, the agency recognizes that the first question that must be addressed is whether there is a need for such regulations or whether part 110 (21 CFR part 110) continues to be adequate. The agency also recognizes that if it decides that there is a need for CGMP regulations, certain issues were not addressed in the submission, and that other interested parties, such as consumers, segments of the industry not represented by the manufacturers and trade associations who submitted the outline, and the health care community, should have an opportunity to provide comment before the agency developed a proposal. Therefore, the agency is issuing this notice to solicit comments and other information on whether it should propose new CGMP regulations for dietary supplements and, if it should, what those regulations should include. Based on the submission and the comments that the agency receives in response to this notice, FDA will consider whether to develop a proposed rule that is designed to establish CGMP that will ensure that dietary supplements are produced under conditions that will result in a safe and properly labeled product but that does not impose any unnecessary burden on the industry.

II. The Industry Submission

A. Introduction

On November 30, 1995, FDA met with representatives of the dietary supplement industry at their request (Ref. 1). At that meeting, the industry representatives submitted a document that outlined suggested CGMP for dietary supplements (Ref. 2). The objective of the CGMP, as stated by the industry representatives, are to ensure that consumers are provided with dietary supplement products that: Are safe and not adulterated or misbranded; (2) have the identity and provide the quantity of dietary ingredients declared in labeling; and (3) meet the quality specifications that the supplement is represented to meet. The industry submission was patterned after the CGMP for food regulation contained in part 110, but also contained requirements beyond those in part 110 that the industry representatives stated that they "consider essential to the manufacture of safe and properly labeled dietary supplements." FDA is publishing the industry suggested dietary supplements CGMP and soliciting comments from industry, consumers, and other interested parties on the need for dietary supplement CGMP regulations and on the requirements that should be included in such regulations.

B. The Industry Draft

The text of the industry suggested dietary supplements CGMP follows:

Good Manufacturing Practices (GMP's) for Dietary Supplements: Statement of Purpose

This document describes Good Manufacturing Practices to be followed in the manufacturing and control operations for dietary supplements and dietary ingredients. The objective of these Good Manufacturing Practices is to assure that consumers are provided with safe dietary supplement products which are not adulterated or misbranded, which have the identity and provide the quantity of dietary ingredients declared in labeling, and which meet the quality specifications that the supplement is represented to meet.

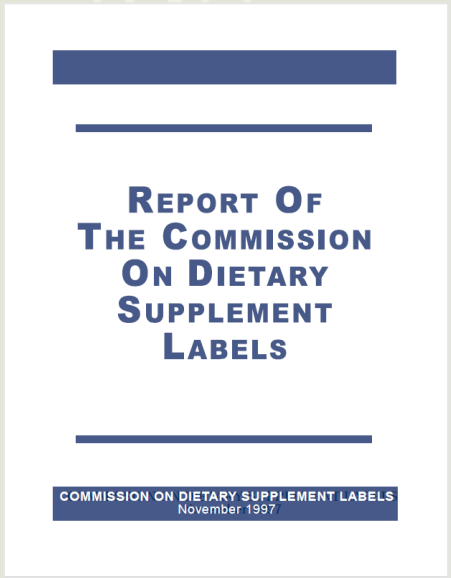
The Food, Drug, and Cosmetic Act defines dietary supplements in section 201(ff). Dietary supplements include a broad spectrum of product forms and a broad spectrum of dietary ingredients. Dietary ingredients may include vitamins; minerals; herbs or other botanicals; amino acids; other dietary substances used to supplement the diet; and concentrates, metabolites, constituents, extracts, or combinations of these. Product forms include tablets, capsules, softgels, gelcaps, liquids, and other forms including—under some conditions—conventional food forms. These Good Manufacturing Practices are intended to encompass all of these types of products. In some cases, judgment may be required in determining the applicability of a specific provision to a particular product or class of products.

Dietary supplements in the physical form of conventional food shall comply with these

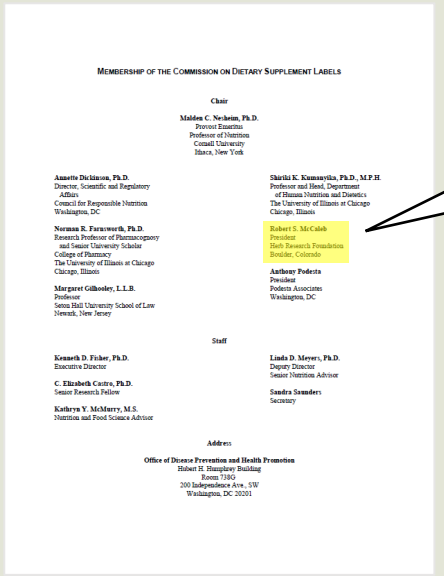
"The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. **Such regulations** shall be modeled after current good manufacturing practice regulations for food and **may not impose standards for which there is no current and generally available analytical methodology**."

Report of the Commission on Dietary Supplement Labels (1997)

COMMISSION MEMBERS


REPORT OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS

COMMISSION ON DIETARY SUPPLEMENT LABELS
November 1997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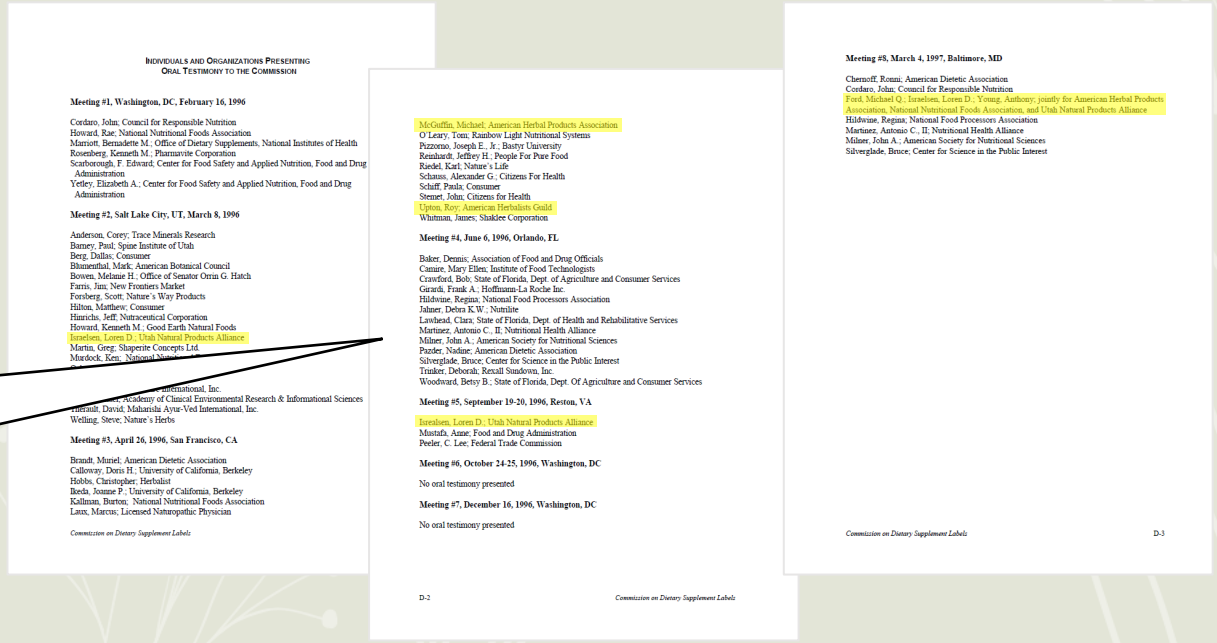
Washington, DC 20201

Robert S. McCaleb
President
Herb Research Foundation
Boulder, Colorado

INDIVIDUAL AND ORGANIZATIONS PRESENTING ORAL TESTIMONY TO THE COMMISSION


INDIVIDUALS AND ORGANIZATIONS PRESENTING ORAL TESTIMONY TO THE COMMISSION

Meeting #1, Washington, DC, February 16, 1996

Cordaro, John; Council for Responsible Nutrition
Howard, Rae; National Nutritional Foods Association
Marriott, Bernadette M.; Office of Dietary Supplements, National Institutes of Health
Rosenberg, Kenneth M.; Pharmavite Corporation
Scarborough, F. Edward; Center for Food Safety and Applied Nutrition, Food and Drug Administration
Yetley, Elizabeth A.; Center for Food Safety and Applied Nutrition, Food and Drug Administration

Meeting #2, Salt Lake City, UT, March 8, 1996

Anderson, Corey; Trace Minerals Research
Barney, Paul; Spine Institute of Utah
Berg, Dallas; Consumer
Blumenthal, Mark; American Botanical Council
Bowen, Melanie H.; Office of Senator Orrin G. Hatch
Farris, Jim; New Frontiers Market
Forsberg, Scott; Nature's Way Products
Hilton, Matthew; Consumer
Hinrichs, Jeff; Nutraceutical Corporation
Howard, Kenneth M.; Good Earth Natural Foods
Israelsen, Loren D.; Utah Natural Products Alliance
Martin, Greg; Shaperite Concepts Ltd.
Murdock, Ken; National Nutritional Foods Association

Academy of Clinical Environmental Research & Informational Sciences
Vitrault, David; Maharishi Ayur-Ved International, Inc.
Welling, Steve; Nature's Herbs

Meeting #3, April 26, 1996, San Francisco, CA

Brandt, Muriel; American Dietetic Association
Calloway, Doris H.; University of California, Berkeley
Hobbs, Christopher; Herbalist
Ikeda, Joanne P.; University of California, Berkeley
Kallman, Burton; National Nutritional Foods Association
Laux, Marcus; Licensed Naturopathic Physician

Commission on Dietary Supplement Labels

McGuffin, Michael; American Herbal Products Association
O'Leary, Tom; Rainbow Light Nutritional Systems
Pizzorno, Joseph E., Jr.; Bastyr University
Reinhardt, Jeffrey H.; People For Pure Food
Riedel, Karl; Nature's Life
Schauss, Alexander G.; Citizens For Health
Schiff, Paula; Consumer
Steuer, John; Citizens for Health
Upton, Roy; American Herbalists Guild
Whitman, James; Shaklee Corporation

Meeting #4, June 6, 1996, Orlando, FL

Baker, Dennis; Association of Food and Drug Officials
Canure, Mary Ellen; Institute of Food Technologists
Crawford, Bob; State of Florida, Dept. of Agriculture and Consumer Services
Girardi, Frank A.; Hoffmann-La Roche Inc.
Hildwine, Regina; National Food Processors Association
Jahner, Debra K.W.; Nutrilite
Lawhead, Clara; State of Florida, Dept. of Health and Rehabilitative Services
Martinez, Antonio C., II; Nutritional Health Alliance
Milner, John A.; American Society for Nutritional Sciences
Pander, Nadine; American Dietetic Association
Silverglade, Bruce; Center for Science in the Public Interest
Trinker, Deborah; Rexall Sundown, Inc.
Woodward, Betsy B.; State of Florida, Dept. Of Agriculture and Consumer Services

Meeting #5, September 19-20, 1996, Reston, VA

Israelsen, Loren D.; Utah Natural Products Alliance
Mustafa, Anne; Food and Drug Administration
Peeler, C. Lee; Federal Trade Commission

Meeting #6, October 24-25, 1996, Washington, DC

No oral testimony presented

Meeting #7, December 16, 1996, Washington, DC

No oral testimony presented

D-2 *Commission on Dietary Supplement Labels*

Meeting #8, March 4, 1997, Baltimore, MD

Chernoff, Ronni; American Dietetic Association
Cordaro, John; Council for Responsible Nutrition
Ford, Michael Q.; Israelsen, Loren D.; Young, Anthony; jointly for American Herbal Products Association, National Nutritional Foods Association, and Utah Natural Products Alliance
Hildwine, Regina; National Food Processors Association
Martinez, Antonio C., II; Nutritional Health Alliance
Milner, John A.; American Society for Nutritional Sciences
Silverglade, Bruce; Center for Science in the Public Interest

Commission on Dietary Supplement Labels D-3

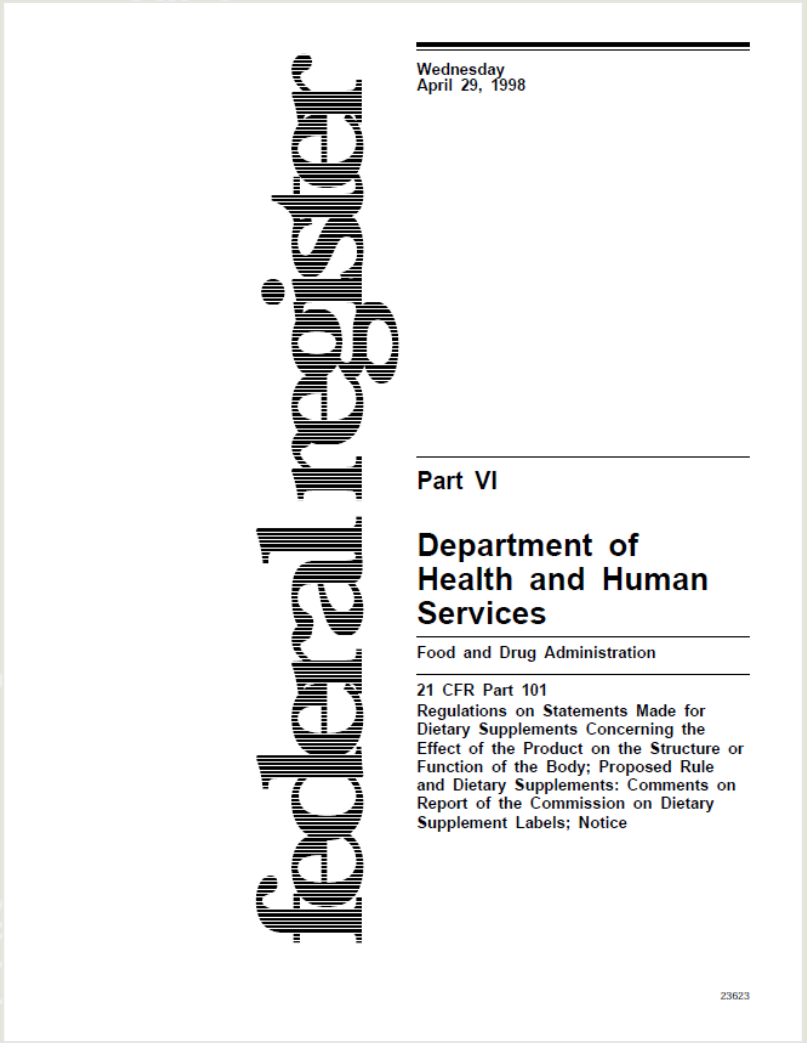
Israelsen, Loren D.; Utah Natural Products Alliance

McGuffin, Michael; American Herbal Products Association

Upton, Roy; American Herbalists Guild

Ford, Michael Q.; Israelsen, Loren D.; Young, Anthony; jointly for American Herbal Products Association, National Nutritional Foods Association, and Utah Natural Products Alliance

Health Claims for Supplements (1998)



federal register

Wednesday
April 29, 1998

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Proposed Rule and Dietary Supplements: Comments on Report of the Commission on Dietary Supplement Labels; Notice

23623

Federal Register / Vol. 63, No. 82 / Wednesday, April 29, 1998 / Rules and Regulations 23627

comment on the basis for the distinction between maintaining normal function and preventing or treating abnormal function and on factors that help distinguish between claims relating to normal, healthy function that do not imply disease treatment or prevention and those that do. Because of the Commission's concerns that claims relating to maintaining healthy cholesterol levels raise particularly difficult issues (the report, p. 37), FDA seeks comment on these claims.

3. Certain natural states, such as pregnancy, aging, or the menstrual cycle, that are themselves not "diseases," are sometimes associated with abnormalities that are characterized by a specific set of signs or symptoms, and thus meet the proposed definition of disease. Under proposed § 101.93(g)(2)(iii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body, such as toxemia of pregnancy, premenstrual syndrome, or abnormalities associated with aging such as presbyopia, decreased sexual function, Alzheimer's disease, or hot flashes. Claims that did not refer to a recognizable abnormality resulting from a natural state or to its signs or symptoms (e.g., "for men over 50 years old," and "to meet nutritional needs during pregnancy") would not be disease claims under this criterion. These examples do not include references to specific abnormalities or symptoms. FDA thus believes that they would not be understood as references to particular diseases.

4. Various aspects of a product's labeling may be used to express or imply that the product will diagnose, cure, mitigate, treat, or prevent disease. Under proposed § 101.93(g)(2)(iv), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on disease through one or more of the following factors:

(a) The name of the product (e.g., "Carpaltum" (carpal tunnel syndrome), "Raynaudin" (Raynaud's phenomenon), "Hepatacure" (liver problems)). Names that did not imply an effect on a disease, such as "Cardiohealth" and "Heart Tabs," would not constitute disease claims;

(b) Statements about the formulation of the product, including a claim that the product contained an ingredient that has been regulated primarily by FDA as a drug and is well known to consumers for its use in preventing or treating a disease (e.g., aspirin, digoxin, or laetrile). FDA notes that this proposed rule is not intended to interpret section 201(ff)(3)(A) of the act (21 U.S.C. 321(ff)(3)(A)), and that a product may be included in or excluded from the definition of "dietary supplement" under that provision regardless of whether the statement made for the product under section 403(r)(6) of the act meets the criteria specified here;

(c) Citation of a title of a publication or other reference, if the title refers to a disease use. For example, labels [illegible] a vitamin E product [illegible] entitled "Serial Coronary Angiographic Evidence That Antioxidant Vitamin Intake Reduces Progression of Coronary Artery Atherosclerosis," would create a disease claim under this criterion;

(d) Use of the term "disease" or "diseased;" or

(e) Otherwise suggesting an effect on disease by use of pictures, vignettes, symbols, or other means (e.g., electrocardiogram tracings, pictures of organs that suggest prevention or treatment of a disease state, the prescription symbol (Rx), or any reference to prescription use). A picture of a body would not constitute a disease claim under this criterion.

5. Certain product class names are so strongly associated with diagnosis, cure, mitigation, treatment or prevention of a disease or diseases, that a claim that a product belonged to such a class would be understood as a disease claim. Under proposed § 101.93(g)(2)(v), a statement would be considered a disease claim if it claimed that the product belonged in a class of products recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure, or prevent a disease (e.g., claims that the product was an "antibiotic," a "laxative," an "analgesic," an "antiviral," a "diuretic," an "antimicrobial," an "antiseptic," an "antidepressant," or a "vaccine"). The foregoing examples do not constitute an exclusive list of product class names that convey disease claims. Claiming that a product was in a class that is not recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure or prevent disease (e.g., an "energizer," a "rejuvenative," a "revitalizer," or an "adaptogen") would not constitute a disease claim under this criterion.

6. A statement may imply that a dietary supplement has an effect on disease by claiming that the effect of the dietary supplement is the same as that of a recognized drug or disease therapy. A statement may also imply an effect on disease by suggesting that the dietary supplement should be used as an adjunct to a recognized drug or disease therapy in the treatment of a disease. In both cases, the statement implies that the dietary supplement is intended for the same purpose as the drug or disease therapy, i.e., for the diagnosis, cure, mitigation, treatment, or prevention of disease. Under proposed § 101.93(g)(2)(vi) and (g)(2)(vii), a statement would be consid[illegible] disease claim [illegible] for a disease (e.g., "Herbal Prozac") or that it augmented a particular therapy or drug action (e.g., "use as part of your diet when taking insulin to help maintain a healthy blood sugar level"). A claim that did not identify a specific drug, drug action, or therapy (e.g., "use as a part of your weight loss plan") would not constitute a disease claim under this criterion.

7. A statement may contain an express or implied disease claim if it suggests that the product cures, mitigates, treats or prevents a disease or diseases by augmenting the body's own disease-fighting capabilities. Under proposed § 101.93(g)(2)(viii), a statement would be considered a disease claim if it explicitly or implicitly claimed a role in the body's response to a disease or to a vector of disease. A vector of disease is an organism or object that is able to transport or transmit to humans an agent, such as a virus or bacterium, that is capable of causing disease in man. A claim that a product "supports the body's antiviral capabilities" or "supports the body's ability to resist infection" would constitute a disease claim under this criterion. Infections are well-known disease states that result from the action of pathogenic (disease-causing) microorganisms, such as bacteria and viruses, and are deviations from and impairments of the normal structure and/or function of the body with characteristic signs and symptoms. Claims that a product is intended to affect the body's ability to kill or neutralize pathogenic microorganisms, or to mitigate the consequences of the action of pathogenic microorganisms on the body (i.e., the signs and symptoms of infection) are disease claims because they are claims exclusively associated with the body's ability to prevent or respond to infectious diseases. A more general reference to an effect on a body system that has several functions, only one of which is resistance to disease, would not constitute a disease claim under this criterion (e.g., "supports the immune system").

Certain natural states, such as pregnancy, aging, or the menstrual cycle, that are themselves not "diseases," are sometimes associated with abnormalities that are characterized by a specific set of signs or symptoms, and thus meet the proposed definition of disease.

NDI Draft Guidance (2011)

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm

Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues

Contains Nonbinding Recommendations
Draft-Not for Implementation

July 2011

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov[2]. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2375.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
July 2011

Contains Nonbinding Recommendations
Draft-Not for Implementation

United States Senate
WASHINGTON, DC 20510

December 22, 2011

Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
109903 New Hampshire Ave.
Building 1, Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As the principle authors of the Dietary Supplement Health and Education Act of 1994 (DSHEA), we write to express our significant concern regarding the Food and Drug Administration's (FDA) draft guidance for industry entitled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which the agency published on July 5, 2011. For the reasons outlined below, we urge the FDA to withdraw this guidance and begin work on a new draft that will provide needed clarification on what constitutes a New Dietary Ingredient (NDI), but does not undermine the balance Congress struck in DSHEA to provide consumers with access to safe, affordable dietary supplement products.

When Congress included language in the Food Safety Modernization Act (FSMA) directing FDA to clarify when a dietary supplement ingredient is a new dietary ingredient, the expectation was that the guidance would be consistent with DSHEA. Unfortunately, the draft guidance serves to undermine DSHEA in a number of important respects.

For example, the draft guidance would require a manufacturer to submit an NDI notification for every dietary supplement containing an NDI. This is directly contrary to the language of DSHEA, which requires notification only of the intent to use an NDI. The FDA's misinterpretation of this provision is far from harmless. Indeed, this burdensome requirement would impose substantial, additional costs on manufacturers without providing additional safety benefits, and would undermine the access to safe, affordable dietary supplement products that DSHEA was designed to ensure. Similarly, the draft guidance attempts to assert that synthetic copies of botanicals can never be a dietary ingredient, an assertion that is wholly without statutory basis, and in fact contradicts longstanding FDA policy. The draft guidance also unduly limits the types of physical modifications that do not result in "chemically altering" a dietary ingredient by incorrectly construing the list in DSHEA legislative history as an exclusive rather than illustrative list. Furthermore, it diverges from our intent by including only ingredients that were marketed before enactment of DSHEA in the form of dietary supplements as "old dietary ingredients." The term dietary supplement wasn't even defined prior to DSHEA.

2011 letter to FDA Commissioner Margaret Hamburg from Senators Harkin & Hatch

Because of these and other concerns, we urge FDA to immediately withdraw this guidance and start the process of crafting a new document that addresses these and other concerns. As part of that process, we would ask that you direct your staff to sit down with our staff early in January to discuss these concerns in more detail.

Thank you for your attention to this matter. We look forward to your prompt reply. If you have any questions, please have your staff contact Jenelle Krishnamoorthy with Senator Harkin and Hayden Rhudy with Senator Hatch.

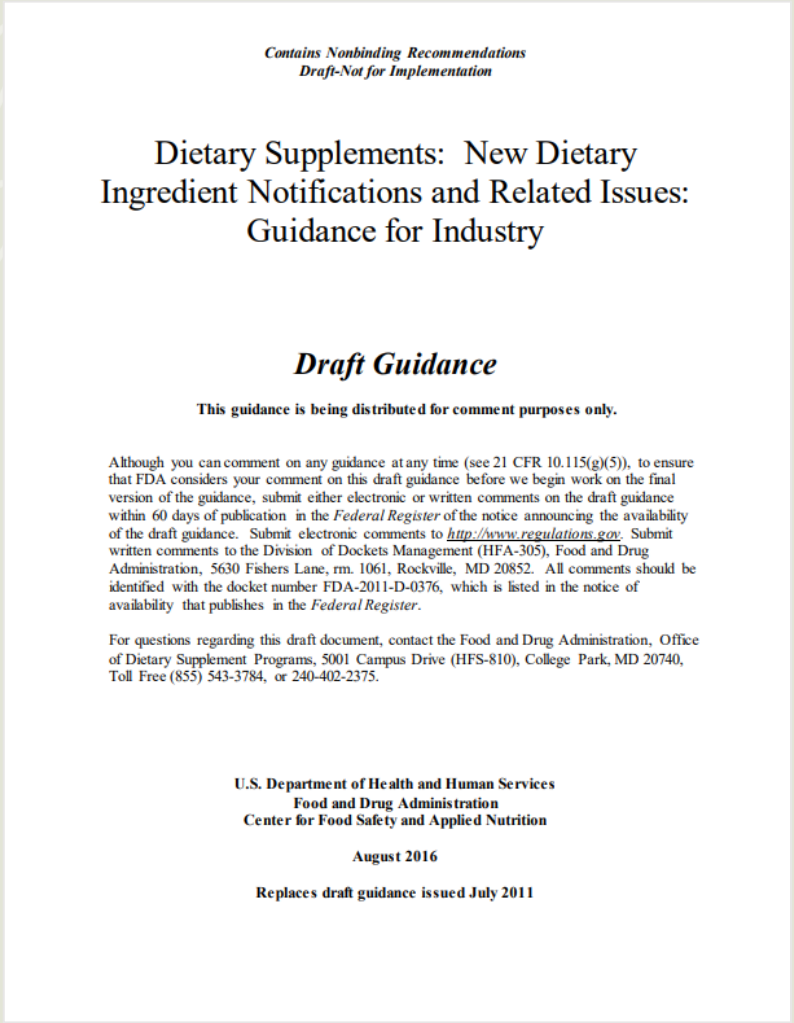
Sincerely,

Tom Harkin
U.S. Senator

Orrin G. Hatch
U.S. Senator

Cc: Jeanne Ireland

NDI Draft Guidance (2016)



Contains Nonbinding Recommendations
Draft-Not for Implementation

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

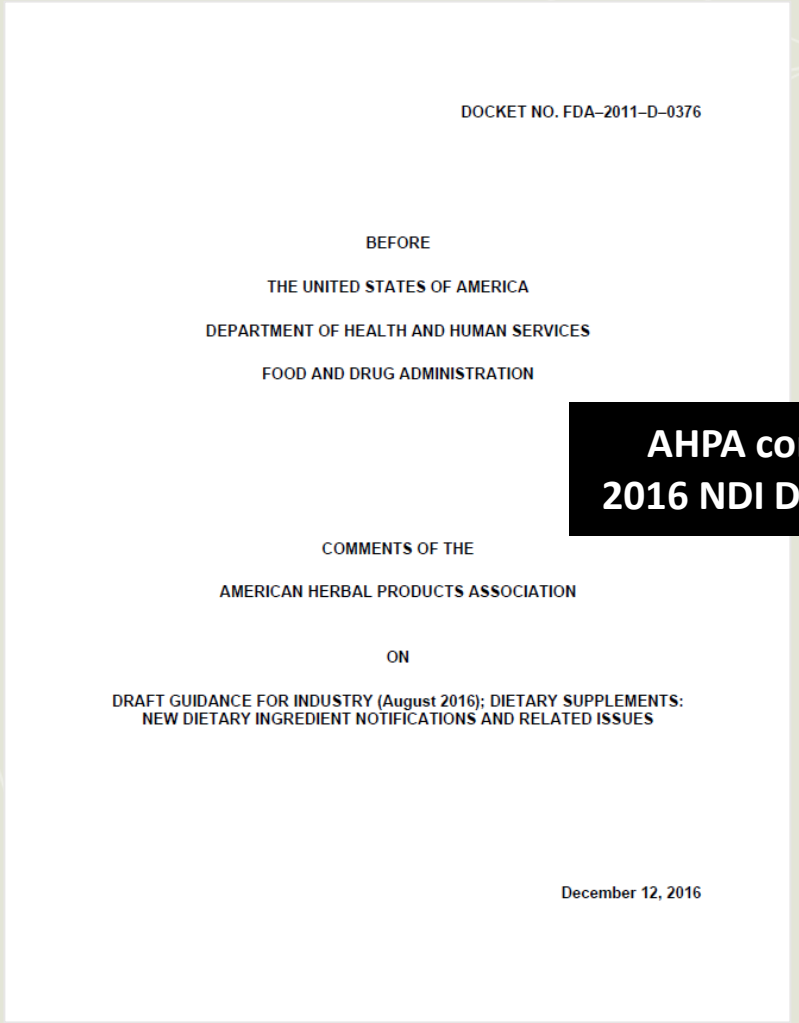
Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2011-D-0376, which is listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Food and Drug Administration, Office of Dietary Supplement Programs, 5001 Campus Drive (HFS-810), College Park, MD 20740, Toll Free (855) 543-3784, or 240-402-2375.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

August 2016

Replaces draft guidance issued July 2011



DOCKET NO. FDA–2011–D–0376

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

AHPA comments on 2016 NDI Draft Guidance

COMMENTS OF THE

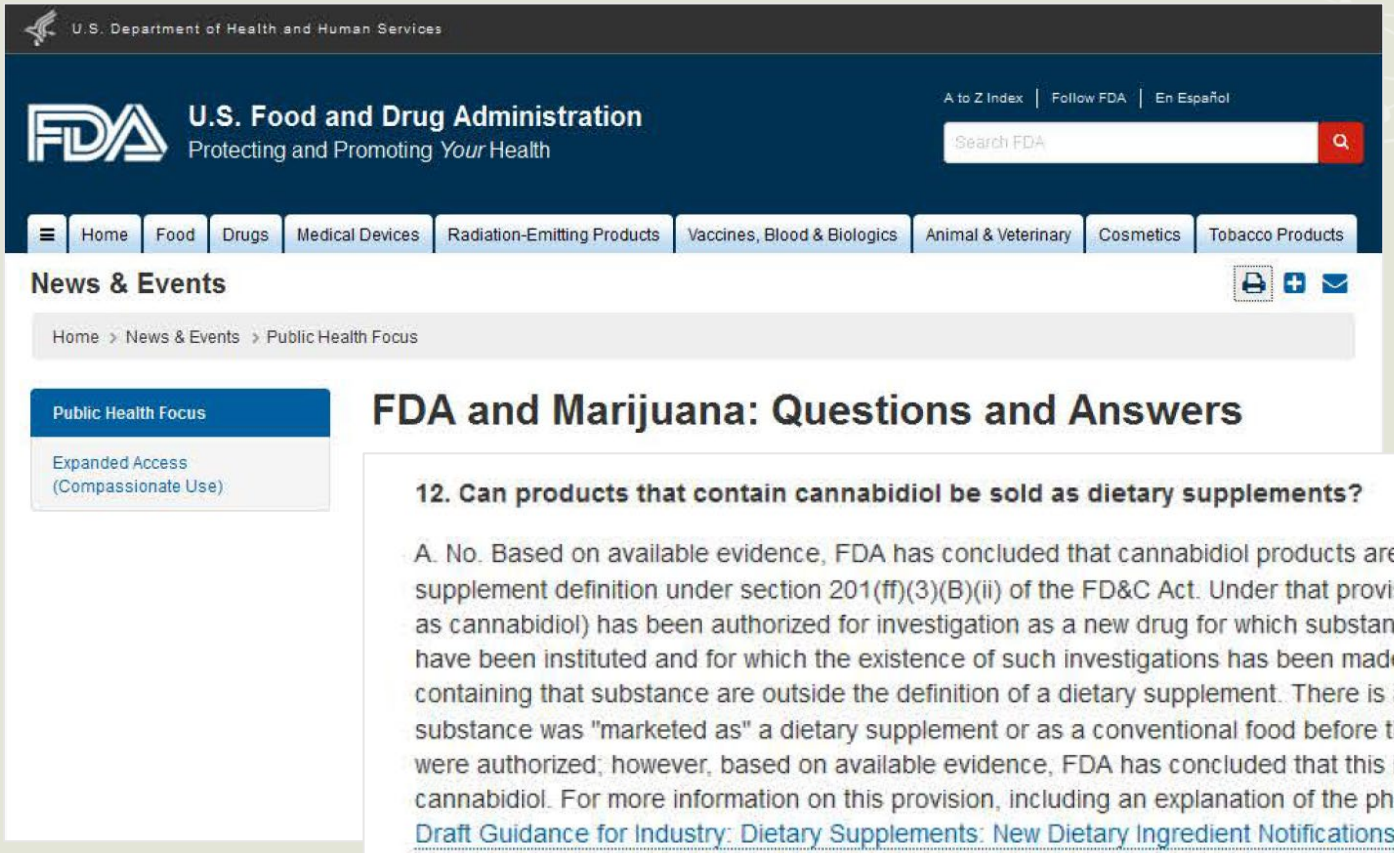
AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

DRAFT GUIDANCE FOR INDUSTRY (August 2016); DIETARY SUPPLEMENTS: NEW DIETARY INGREDIENT NOTIFICATIONS AND RELATED ISSUES

December 12, 2016

FDA on CBD (June 15, 2015 – March 8, 2022)



U.S. Department of Health and Human Services

U.S. Food and Drug Administration
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News & Events

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Public Health Focus

Expanded Access (Compassionate Use)

FDA and Marijuana: Questions and Answers

12. Can products that contain cannabidiol be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act. Under that provision, if a substance (such as cannabidiol) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for cannabidiol. For more information on this provision, including an explanation of the phrase "marketed as," see Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.

FDA is not aware of any evidence that would call into question its current conclusion that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue.

N-acetyl-L-cysteine (NAC)

WARNING LETTER

"Vita Heaven, LLC dba Hangover Heaven

MARCS-CMS 593765 – JULY 23, 2020

Share Tweet Linkedin Email Print

Product: Dietary Supplements

Recipient:
Jason Burke, MD
President
"Vita Heaven, LLC dba Hangover Heaven
3281 South Highland Drive Suite 806
Las Vegas, NV 89109
United States

Issuing Office:
Center for Food Safety and Applied Nutrition (CFSAN)
United States

Based on the product label[illegible] your website, it appears that you intend to market your Hangover Heaven Nightlife Prep Supplement product, which contains N-acetyl-L-cysteine (NAC), as a dietary supplement. However, even if your product labeling did not have therapeutic claims that make your product an unapproved new drug, your product could not be a dietary supplement, because it does not meet the definition of dietary supplement under section 201(ff) of the Act [21 U.S.C. § 321(ff)]. FDA has concluded that NAC products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) of the Act [21 U.S.C. § 321(ff)(3)(B)(i)]. Under this provision, if an article (such as NAC) has been approved as a new drug under section 505 of the Act [21 U.S.C. § 355], then products containing that article are outside the definition of a dietary supplement, unless before such approval that article was marketed as a dietary supplement or as a food. NAC was approved as a new drug under section 505 of the Act [21 U.S.C. § 355] on September 14, 1963. FDA is not aware of any evidence that NAC was marketed as a dietary supplement or as a food prior to that date.

FDA has concluded that NAC products are excluded from the dietary supplement definition…

FDA is not aware of any evidence that NAC was marketed as a dietary supplement or as a food prior to [September 14, 1963].

AHPA comments to FDA on NAC

Comments of the American Herbal Products Association on the Citizen Petition of the Natural Products Association Regarding the Regulatory Status of N-acetylcysteine (Dkt. No. FDA-2021-P-0938).

October 8, 2021

The American Herbal Products Association (AHPA) respectfully submits comments in support of the August 18, 2021, citizen petition submitted by Daniel Fabricant on behalf of the Natural Products Association (NPA) (FDA Dkt. No. FDA-2021-P-0938) seeking a determination by the U.S. Food and Drug Administration (FDA) that a product consisting of or containing N-acetylcysteine (NAC)[1] that otherwise meets the definition of "dietary supplement" at 21 U.S.C. § 321(ff) is not excluded from that definition under 21 U.S.C. § 321(ff)(3)(B).

AHPA agrees with NPA that 21 U.S.C. § 321(ff)(3)(B) does not have retroactive effect. As such, this provision does not exclude from the definition of "dietary supplement" products that contain or consist of articles—such as NAC—that were already being marketed as foods or dietary supplements before the enactment of the Dietary Supplement Health and Education Act of 1994, regardless of whether such articles were approved or authorized for investigation as new drugs prior to their marketing in the food supply. Even if FDA disagrees, and without conceding the lawfulness of such a position, AHPA would urge FDA to grant NPA's alternative request to issue a regulation finding that NAC is a lawful dietary supplement pursuant to 21 U.S.C. § 321(ff)(3)(B).

AHPA is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

I. Background

On October 25, 1994, the Dietary Supplement Health and Education Act of 1994 (DSHEA)[2] was enacted to provide a framework under the Federal Food, Drug, and Cosmetic Act (FFDCA) for regulation of dietary supplements as a subcategory of foods. In part, DSHEA defines "dietary supplement" to mean a product (other than tobacco) that: (i) contains a dietary ingredient; (ii) is intended for ingestion to supplement the human diet; (iii) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (iv) is labeled as a dietary supplement. 21 U.S.C. § 321(ff).

The "dietary supplement" definition, however, excludes products that contain or consist of any article (i) "that is approved as a new drug under [section 505 of the FFDCA]" or

[1] NAC is also referred to as N-acetyl-L-cysteine or acetylcysteine.

[2] Pub. L. 103-417, 108 Stat. 4325 (Oct. 25, 1994).

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Docket No. FDA–2021–P–0523
Docket No. FDA–2021–P–0938

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

TENTATIVE RESPONSES TO CITIZEN PETITIONS regarding THE REGULATORY STATUS OF N-ACETYLCYSTEINE

January 25, 2022

AHPA
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Contact Melissa Do, AHPA's Director of Communications, at mdo@ahpa.org with any questions and to get started.

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