Dietary Supplements and Claims

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United Natural Products Alliance

4Life
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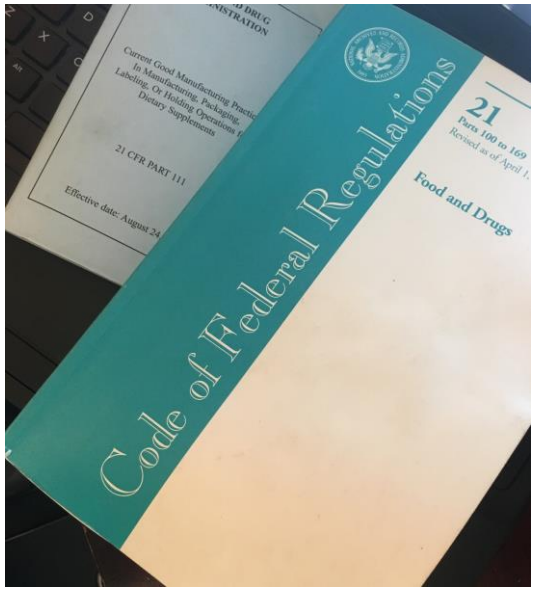
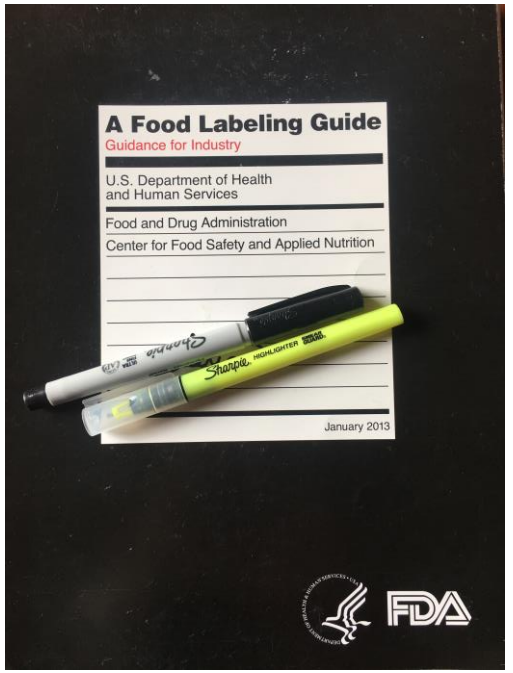
DS Claims Summary

- Food and Drug Administration (FDA)
- Federal Trade Commission (FTC),
  Bureau of Consumer Protection
- Substantiation of claims
  - Global perspective and the European Union (EU)
  - FDA guidance
- Food Safety Modernization Act (FSMA) update

FDA

- Regulations
  - 21 CFR Part 101-Food Labeling
  - Food Drug and Cosmetic Act
- 2017 FDA warning letters
- Regulatory resources and tools
  - *A Food Labeling Guide*
  - Guidance documents





https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf

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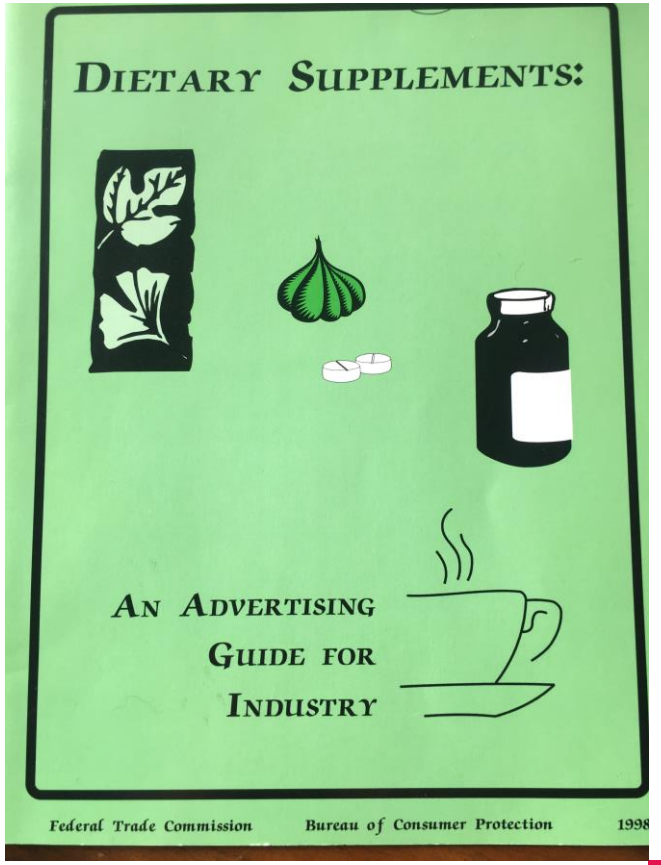
FTC

- *Dietary Supplements: An Advertising Guide for Industry*
- Recent (2017) regulatory action



https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf

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Substantiation of claims

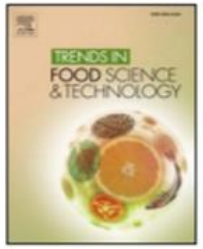
ARTICLE IN PRESS

Trends in Food Science & Technology xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Trends in Food Science & Technology

journal homepage: www.elsevier.com/locate/tifs



Commentary

Recommendations for successful substantiation of new health claims in the European Union

Igor Pravst[a,*], Anita Kušar[a], Katja Žmitek[a], Krista Miklavec[a], Živa Lavriša[a], Liisa Lähteenmäki[b], Viktorija Kulikovskaja[b], Rosalind N. Malcolm[c], Charo Hodgkins[d], Monique M. Raats[d], the REDICLAIM Consortium

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http://www.sciencedirect.com/science/article/pii/S0924224417302315

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Substantiation of claims

- https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm

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Definitions

- Label
- Labeling

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Definitions

Disease [21 CFR 101.93(g)]

"…damage to an organ, structure, or system of the body such that it does not function properly (e.g. cardiovascular disease), or state of health leading to dysfunctioning (e.g. hypertension); except the disease resulting from essential nutrient deficiencies (e.g. scurvy, pellagra) are not included in this definition."

Who cares about claims?

FDA U.S. FOOD & DRUG ADMINISTRATION


Supplement to the Los Angeles and San Francisco
Daily Journal
JUNE 14, 2017
TOP PLAINTIFF LAWYERS
IN CALIFORNIA FOR 2017
David R. Lira
Girardi Keese
Los Angeles
Practice: Product liability, insurance bad faith, negligence, wrongful death

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PART 101 -- FOOD LABELING

Subpart A--General Provisions

Sec. 101.18 Misbranding of food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name composed in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

101.18- Misbranding of food

Three reasons including:

a) False and misleading representation of the product
b) Misrepresenting the ingredients in the product
c) Deceptive Country of Origin (COO) statements

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101.18 (b)
Warning letter example

Your House of Meats brand Shell Macaroni Salad (5 lb. tub) product label contains false or misleading statements [21 CFR 101.18]. Specifically, your product label includes “onion powder” in the ingredient statement; however the formulation for your product reveals that onion powder is not used in the manufacture of this product.

https://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm305233.htm

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101.18 (c)

Country of Origin

- FDA reference: *Compliance Guide: CPG Sec 560.200 Country of Origin Labeling* (updated 2005)
  - "…not required by the Federal Food, Drug, & Cosmetic Act."
  - "This is a requirement of the U.S. Customs and Border Protection (CBP)…"

Map source: https://www.google.com/search?q=global+map&source=lnms&tbm=isch&sa=X&ved=0ahUKEwigw_7p29fXAhVOzGMKHc3ICkEQ_AUICygC&biw=1250&bih=585#imgrc=fwILLohwmKll9M:

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Food Drug and Cosmetic Act (FD&C) Section 343-Misbranded Food

- 21 pages
- 25 section headers, including:

“a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.”

http://uscode.house.gov/view.xhtml?req=Sec.+403%09Sec.+343+-+Misbranded+food&f=treesort&fq=true&num=3&hl=true&edition=prelim&granuleId=USC-prelim-title21-section343

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Food Drug and Cosmetic Act (FD & C) Section 350-Vitamins and Minerals

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 321(ff) of this title (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

http://uscode.house.gov/view.xhtml?req=%22section+350%22+and+food&f=treesort&fq=true&num=3&hl=true&edition=prelim&granuleId=USC-prelim-title21-section350

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343 - Misbranded food

"Dietary supplement" is mentioned 42 times, including:

- Supplement facts and product label expectations
- Validity of claim
- Address or domestic phone for a responsible person to receive a report of serious adverse event
- Other fine print

http://uscode.house.gov/view.xhtml?req=Sec.+403%09Sec.+343+-+Misbranded+food&f=treesort&fq=true&num=3&hl=true&edition=prelim&granuleId=USC-prelim-title21-section343

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2017 regulatory action related to DS claims

For Consumers

Home › For Consumers › Protect Yourself › Health Fraud

Health Fraud

- For Consumers
- Warning Letters - Health Fraud
- Health Fraud Scams - Be Smart, Be Aware, Be Careful (Video)
- Public Notifications and Safety Alerts - Health Fraud
- Recalls - Health Fraud
- Seizures and Injunctions - Health Fraud
- Press Announcements - Health Fraud

Warning Letters - Health Fraud

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Examples of FDA Warning Letters that cite unapproved or unsubstantiated claims, tainted products or other health fraud* - related violations. For all FDA Warning Letters, click here.

Previous Years: 2016 | 2015 | 2014 | 2013 | 2012 | 2011 | 2010 | 2009 | 2008 | 2007

Letter Issue Date	Company Name	Issuing Office	Subject
10/31/2017	Green Roads of Florida LLC	San Juan District Office	New Drug/Misbranded/Cannabidiol(CBD) products
10/31/2017	Herbal Alchemist	Los Angeles District Office	New Drug/Misbranded/Cannabidiol(CBD) products

- Total of 70 WL
- 60 for misbranding
- 87%

https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/ucm255474.htm

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2017 regulatory action related to claims: Warning letter example #1

Unapproved New Drug Violations

Under section 201(g)(1)(C) of the FD&C Act [21 U.S.C. § 321(g)(1)(C)], drugs are defined as articles (other than foods) that are intended to affect the structure or function of the body. The intended use of an article may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution. 21 C.F.R. § 201.128. Your product labeling includes claims that indicate the intended uses of the product, such as "Anabolic & Androgenic," "Extreme Strength & Power," and "Increases Aggression." These claims establish that your "Super DMZ 4.0" product is a drug under section 201(g)(1)(C) of FD&C Act because it is intended to affect the structure or function of the body.

Moreover, the product is a "new drug," as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321 (p)], because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

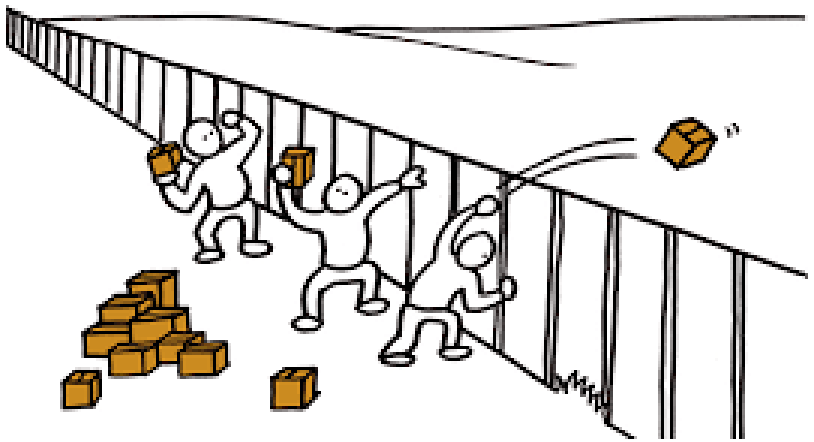
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm582464.htm

2017 regulatory action related to claims WL example #2

Pharmaceutical ingredients in products marketed as dietary supplements

- "Your products are intended to affect the structure or function of the body by, among other things, building muscle and increasing strength. Accordingly, "The Officer (MK-2866)" and "Lieutenant (LGD-4033)" are drugs."

2017 regulatory action related to claims



WL language related to a product marketed as a DS and reclassification as a drug by FDA:

"**Misbranded Drug Violations**

According to section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s)."

Image source: https://www.transitionsc.org/over-the-fence/

2017 regulatory action related to claims WL example #3: Labeling/website

"The claims on your websites establish that the products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act."

2017 regulatory action related to claims WL example #4, from DEN-DO website

Unapproved New Drugs

FDA reviewed your website at the internet address www.mega-pro.com in May, 2017, and have determined that you take orders there for your products, including Chromium Picolinate, Creatine, and DHEA.

The therapeutic claims on your website establish that your Chromium Picolinate, Creatine, and DHEA products are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

Specialty Products Alertness / Energy

- Chromium Picolinate "…play a role in lowering cholesterol, normalizing high blood sugar…"
- DHEA: "…linked DHEA depletion with almost every major degenerative disease…"

https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm576665.htm

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2017 regulatory action related to claims WL example #5

Claims:

Examples of some of the label claims that provide evidence that your Omega-3-Fish Oil is intended for use as a drug include:

"Heart – … helping reduce the risk of arrhythmias and sudden death by heart attack."

"Brain – Better brain function though more efficient neurotransmitters leading to … less likelihood of depression and reduced risk of ADHD in children."

"Joints and Arthritis – Better joint function from reduced inflammation and a reduction in pain."

"Immune System and Cancer – A stronger immune system, proven to be beneficial for … lowered risk of breast and prostate cancer."

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2017 regulatory action related to claims WL Example #5, cont'd

"Digestive System – … improving intestinal health and reducing inflammation assisting those with IBS or Crohn's Disease."

"Diabetes – Fish oil enhances insulin secretion from beta cells in the pancreas, regulating blood sugar levels. DHA plays a protective role in diabetic neuropathy in all forms of diabetes."

Examples of some of the website claims that provide evidence that your Total Estro (33 Diindolymethane) is intended for use as a drug include:

"DIM also exerts numerous anti-carcinogenic (anti-cancer) effects in the body …"

2017 regulatory action related to claims

New Dietary Ingredients:

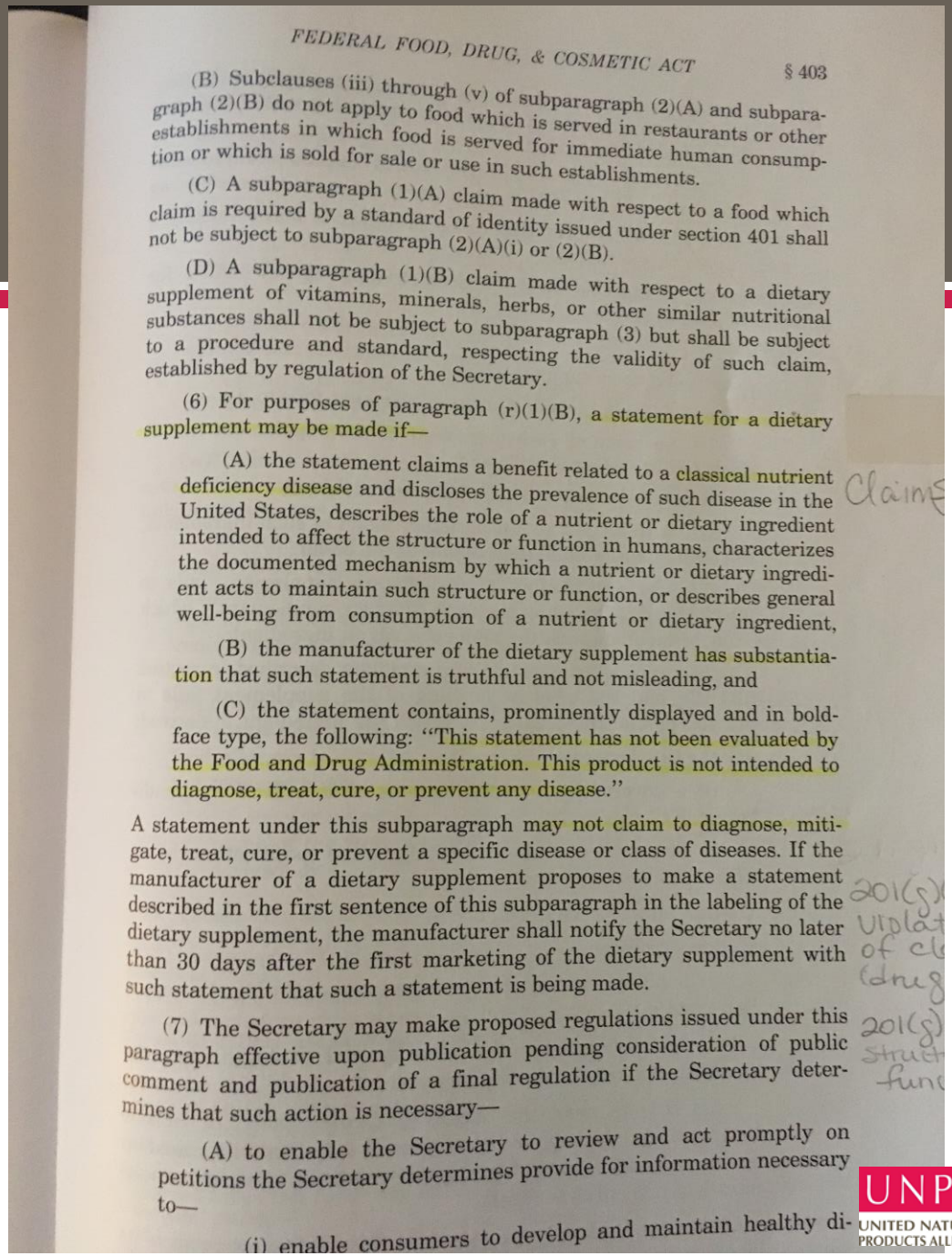
- DMAA

FDA FD&C Act

Section 403-Misbranded Food

… a statement for a dietary supplement may be made if …

A) Classical nutrient deficiency
B) Truthful and not misleading with substantiation
C) Contains “FDA disclaimer” statement



FEDERAL FOOD, DRUG, & COSMETIC ACT § 403

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy di-

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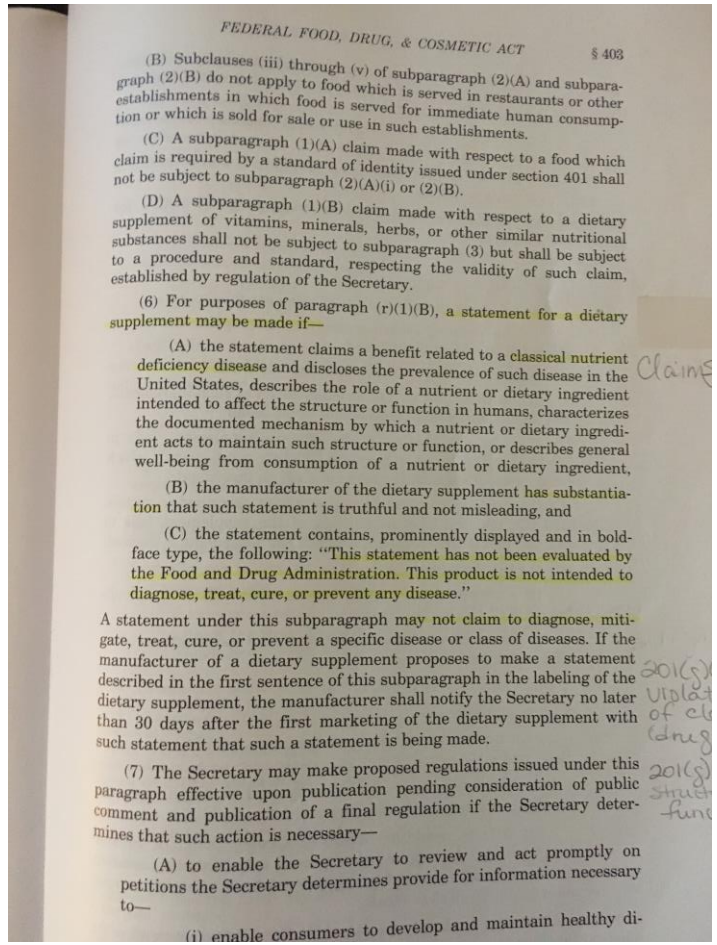
FD&C Act
FDA statement regarding DS claim

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

Statement text must be in bold font.



FEDERAL FOOD, DRUG, & COSMETIC ACT § 403

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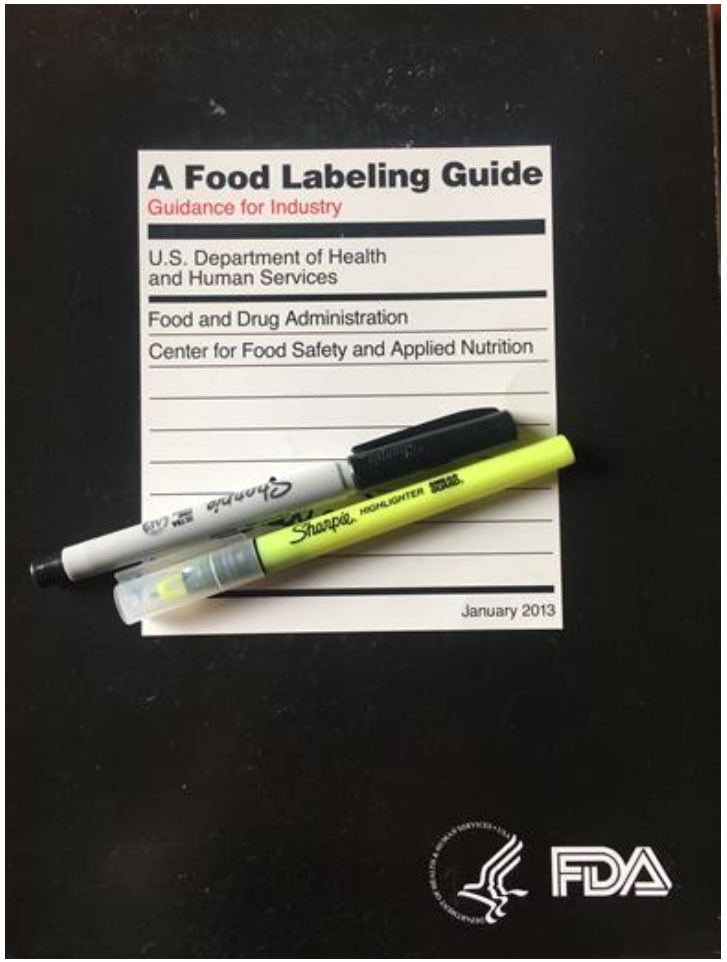
Types of claims

- Health claims
- Qualified health claims
- Structure/function claims
- Nutrient content claims



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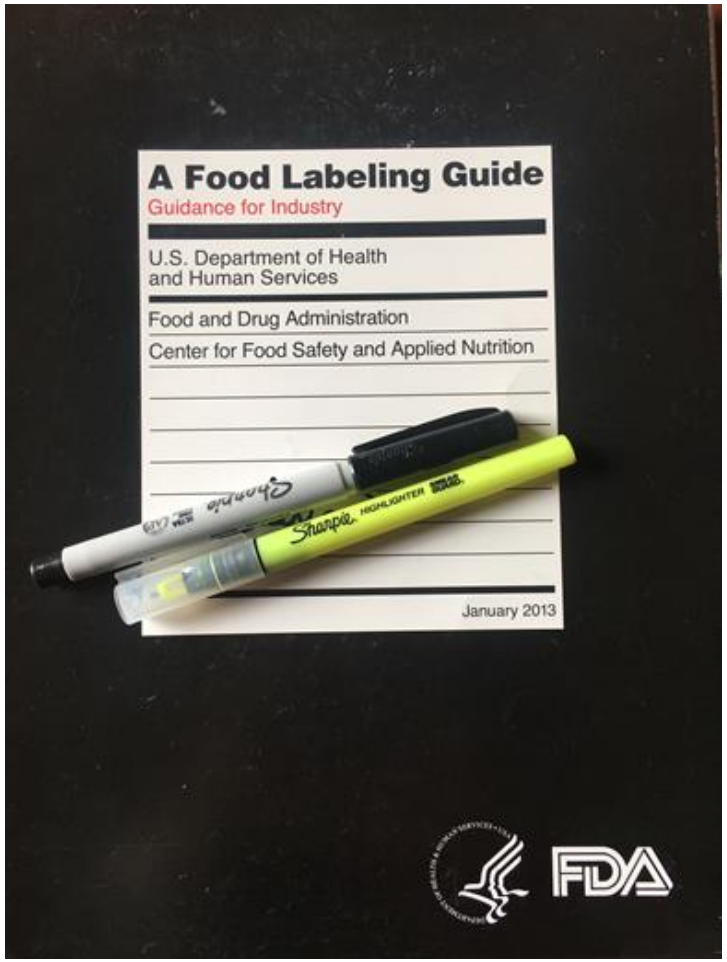
Health Claims

What is a health claim?

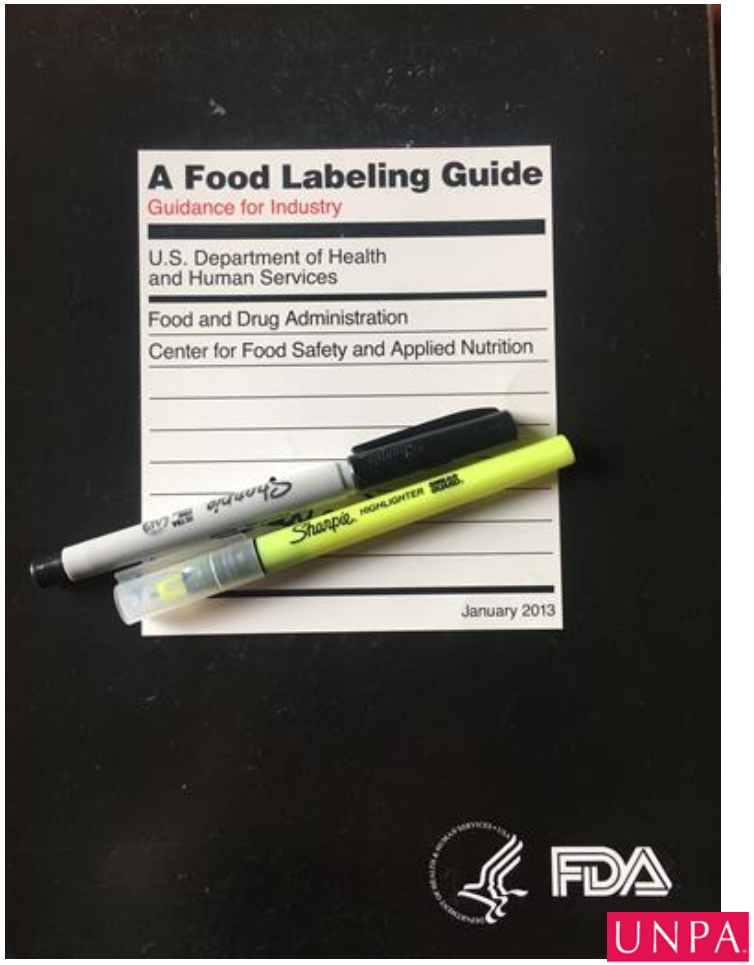
- A health claim is an explicit or implied characterization of a relationship between a substance and a disease or a health-related condition. This type of claim requires significant scientific agreement and must be authorized by FDA. The claim can be a written statement, a "third party" reference, a symbol, or a vignette.
- 21 CFR 101.14(a)(1) and (c)”



Appendix C: Health claims

12 approved health claims as of January 2013, and include:

- Calcium and osteoporosis; and calcium, vitamin D and osteoporosis (21 CFR 101.72)
- Dietary fat and cancer (21 CFR 101.73)
- Folate and neural tube defects (21 CFR 101.79)
- Plant sterol/stanol esters and risk of coronary heart disease (21 CFR 101.83)



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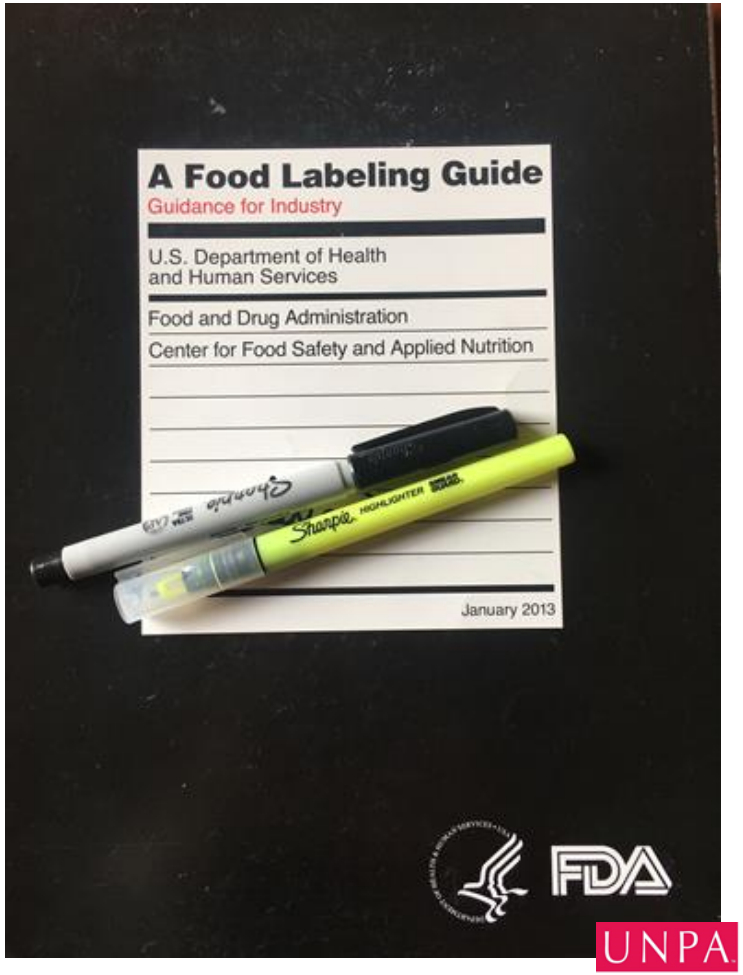
Health claims

- Limited to claims about reducing risk of disease and not about the diagnosis, cure, mitigation, or treatment of disease
- Evaluated by FDA prior to use
- Criteria summarized in 21 CFR 101.9(k)(1), 101.14 (c)-(d) and 101.70
- If a claim is provided in FDA regulation, then it may be used in accordance with the reg



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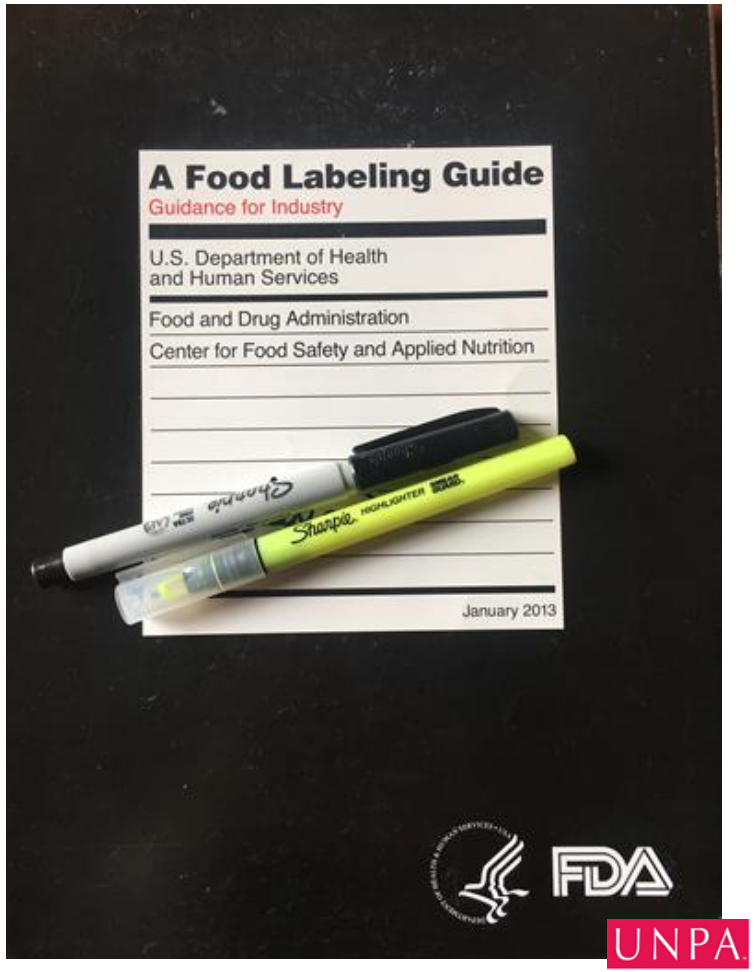
Qualified health claims (QHC)

- 2003
- Less scientific evidence than health claims as long as the claim is not misleading
- Reviewed by FDA



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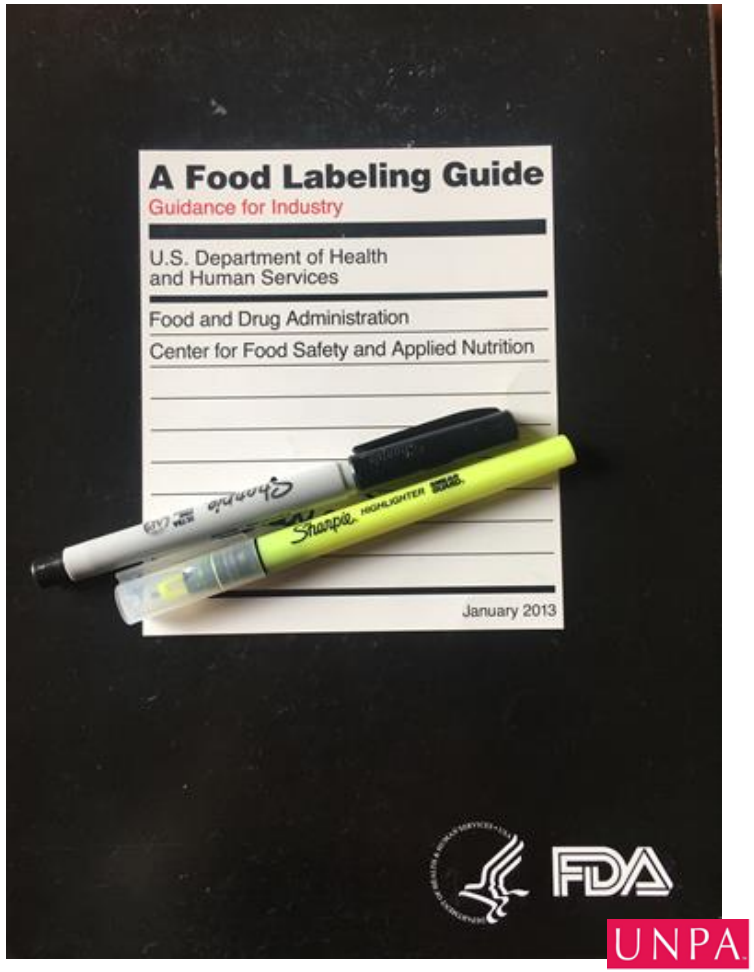
Qualified health claims

"If a letter of enforcement discretion has been issued, FDA does not intend to object to the use of the claim as specified in the letter, provided that the products that bear the claim are consistent with the stated criteria."



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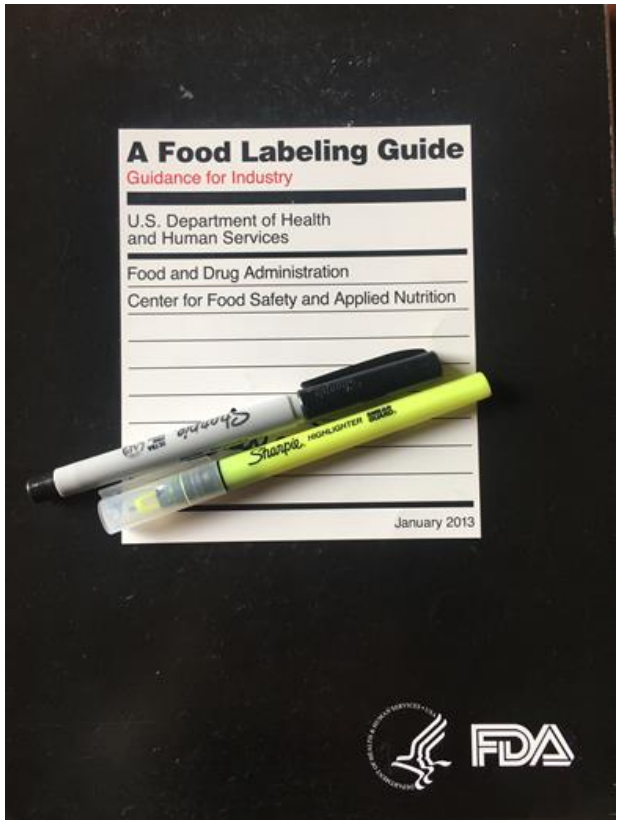
Scientific support and timing

- Health claim = significant scientific agreement (SSA)
- Qualified health claim = "… based on the totality of publicly available scientific evidence (see 21 CFR 101.45)"
- QHC = 270 days after receipt of petition
- Requirements for QHC petition are found in 21 CFR 101.70.



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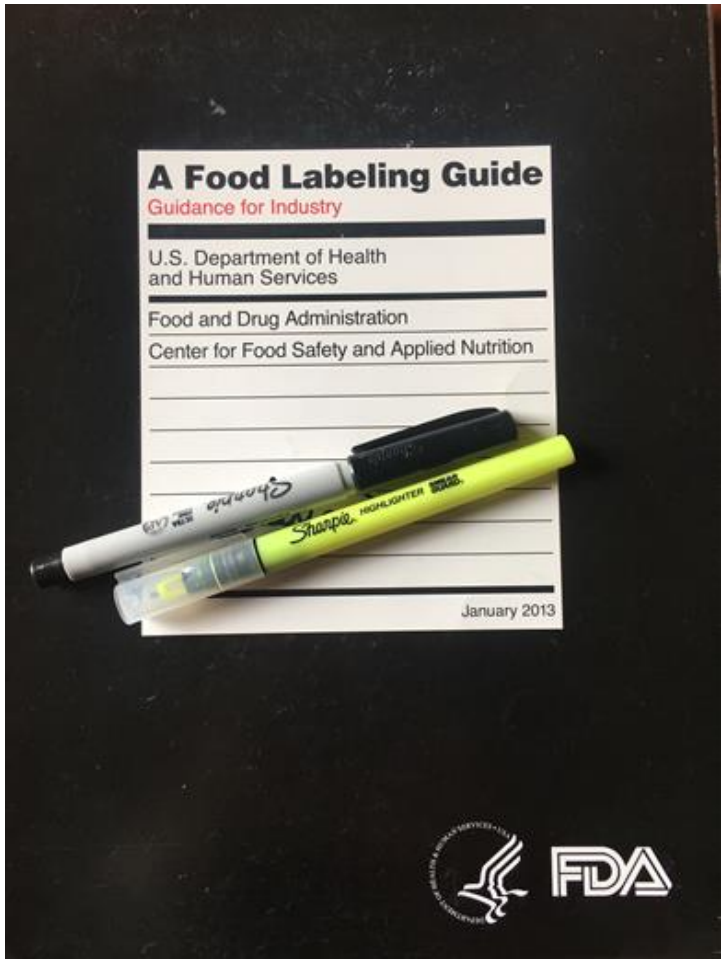
Structure/function claims

- DSHEA 1994 added section 403(r)(6)
- "… states dietary supplements can bear certain statements on its label or its labeling if the claim meets certain requirements"



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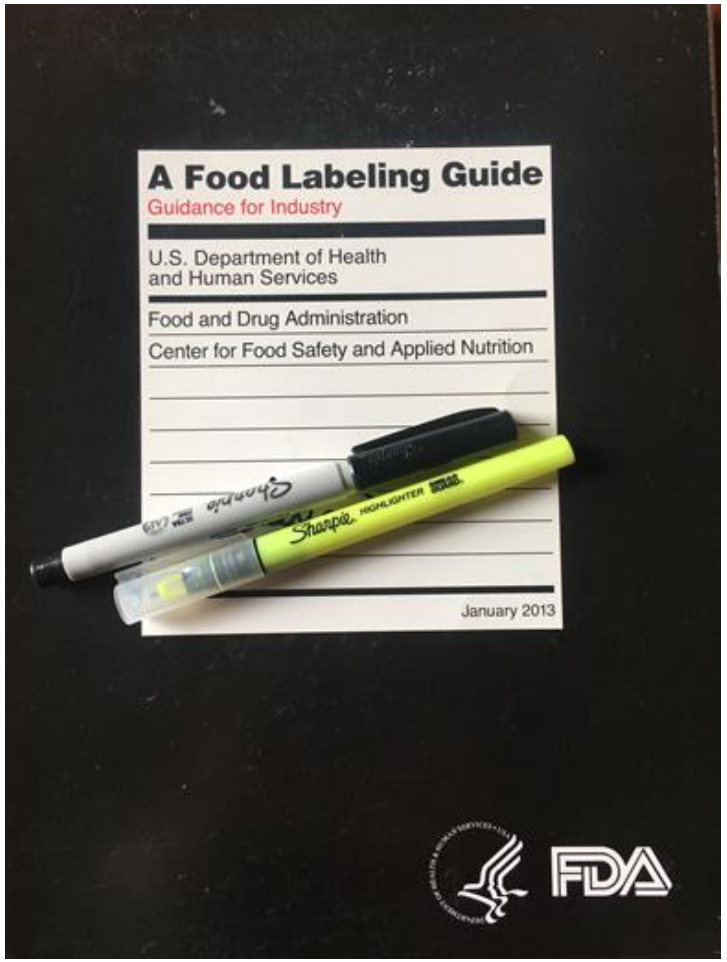
Structure/function claims

Requirements include:

- Describe the role of a nutrient or DI intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function …”



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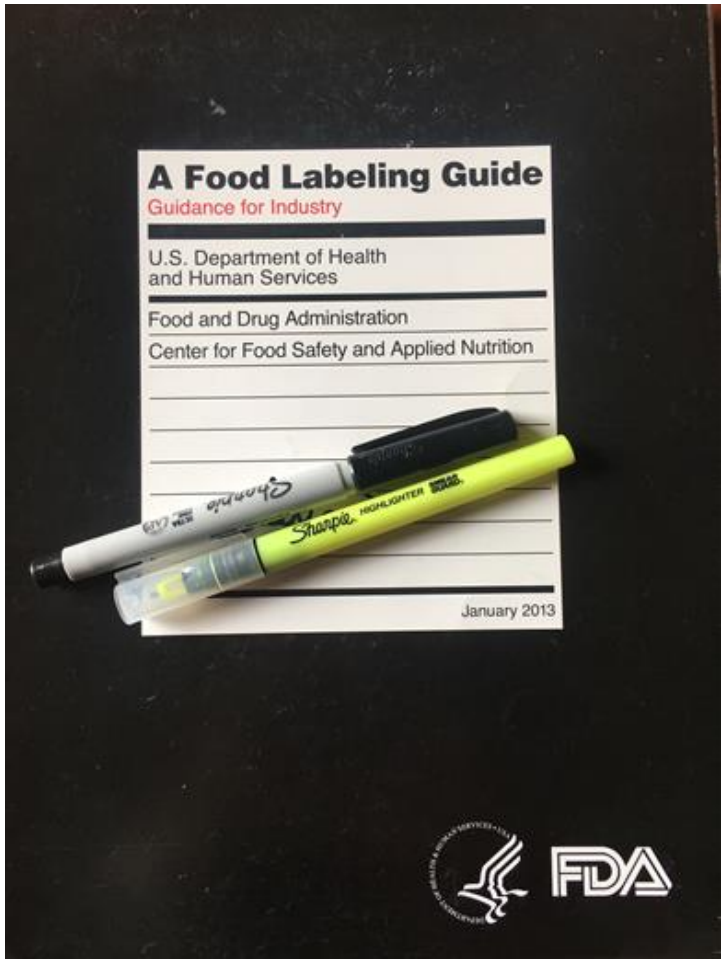
Structure/function claims

Nutritional deficiency

- Example: vitamin C and scurvy
- Or effect of DS in general well-being



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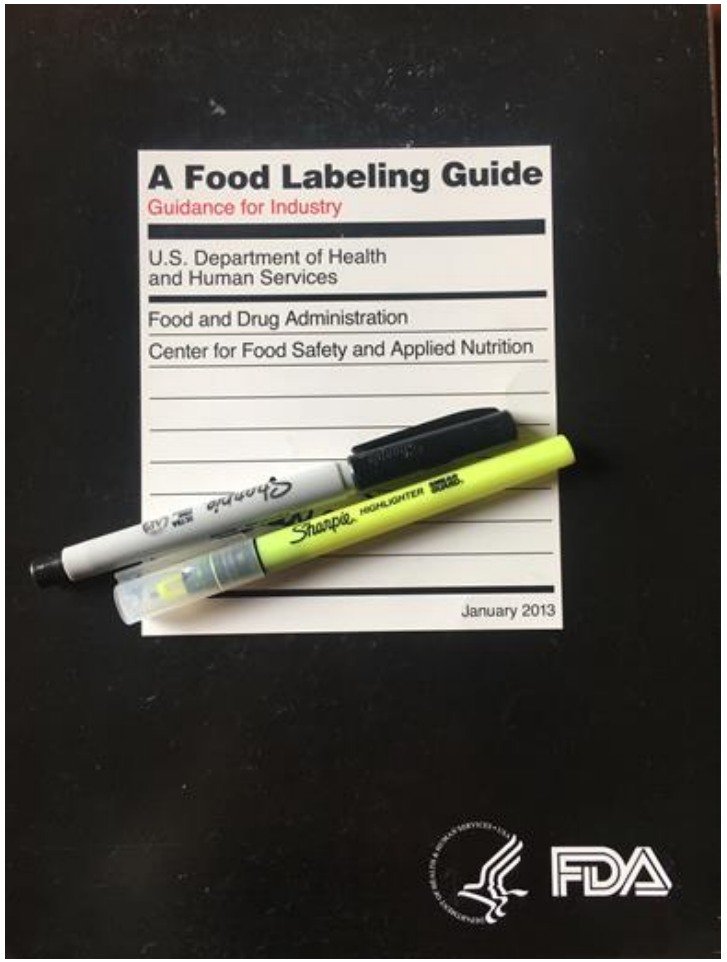
Requirements of structure/function claims

- Must have substantiation that claims is truthful and not misleading
- Notify FDA within 30 days of first marketing the product
- Make the mandatory disclaimer statement on the label



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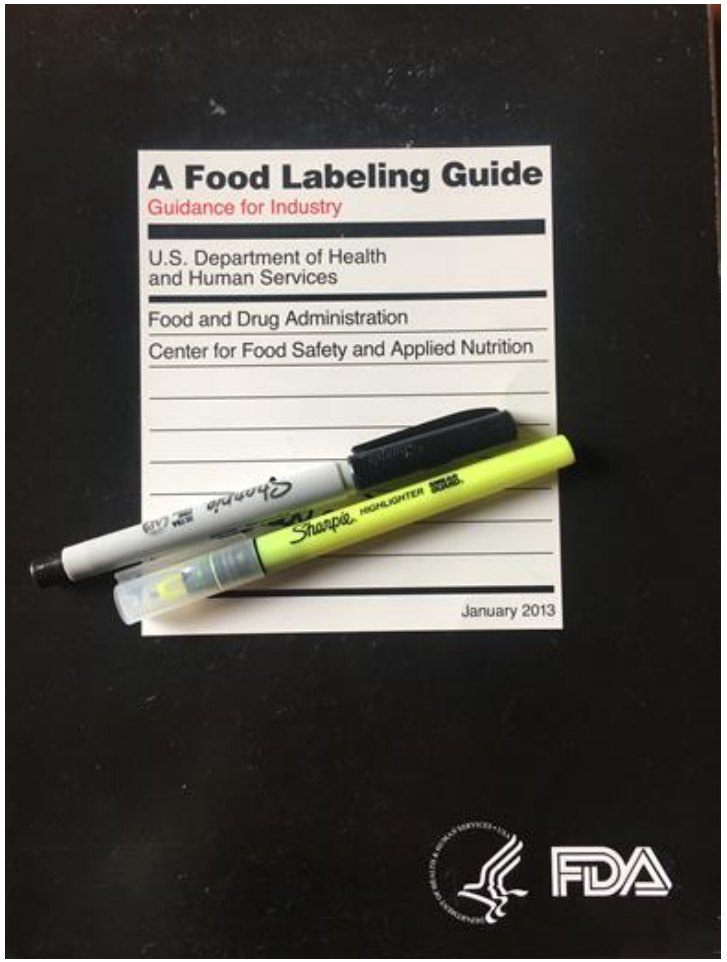
Nutrient content claims

- Appendix A
- Content
  - “Low, free, reduced”
- Nutrient content claims
  - Six definitions
  - Calories, total fat, saturated fat, cholesterol, sodium, and sugars



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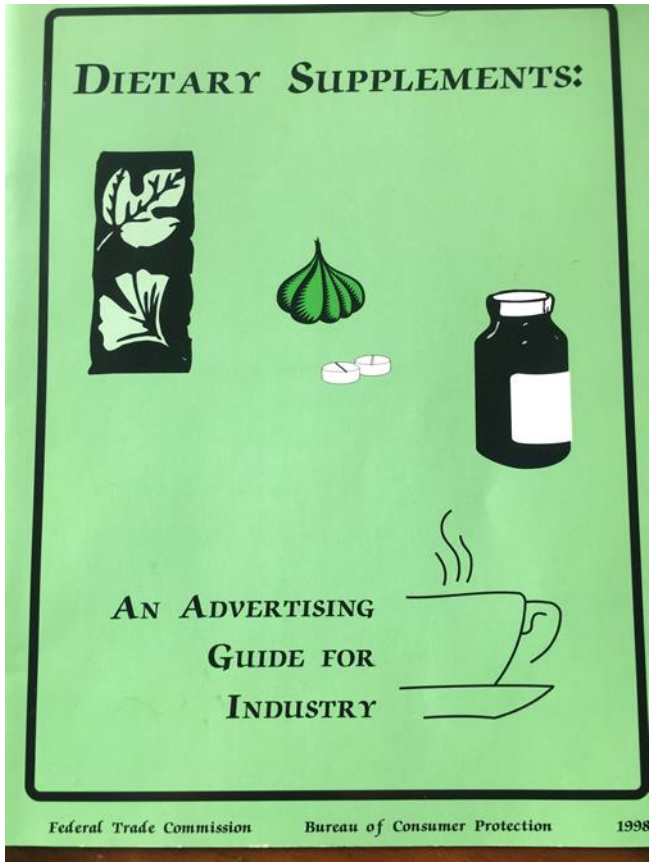
FTC and FDA

- FDA and FTC work together when it comes to claims

- "…long –standing liaison agreement governing the division of responsibilities between the two agency's."



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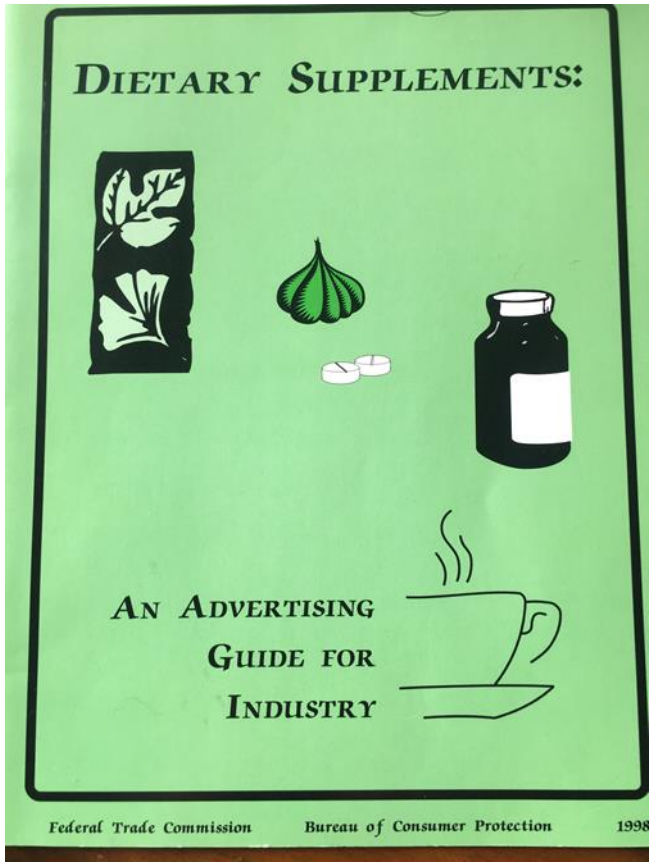
FTC and FDA

- FDA: "…responsibility for claims on product labeling, including packaging, inserts, promotional material distributed at point of sale"

- FTC: "…claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct mail materials.



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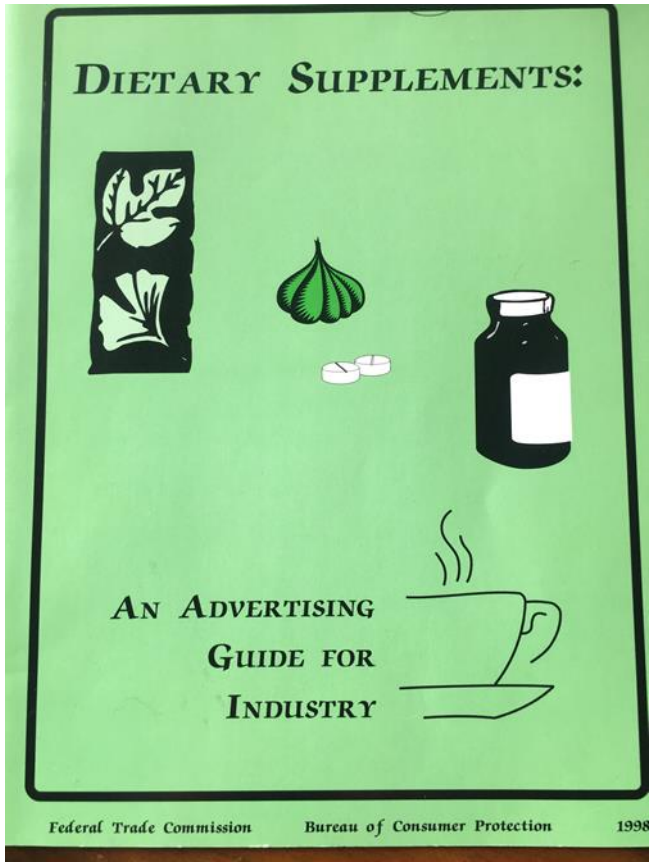
FTC

- "…must be truthful, not misleading, and substantiated."
- "In general, the FTC gives great deference to the FDA determination of whether there is adequate support for a health claim."
- "Furthermore, the FTC and the FDA will generally arrive at the same conclusion when evaluating unqualified health claims."



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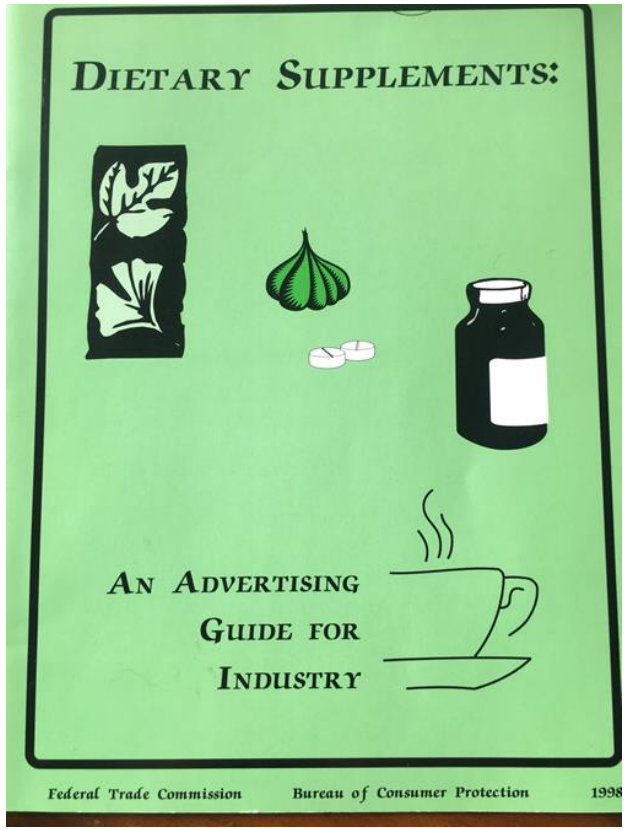
FTC



36 Examples

Example 3

An ad for an herbal supplement makes the claim that the product boosts the immune system to help maintain a healthy nose and throat during the winter season. The ad features the product name "Cold Away" and includes images of people sneezing and coughing.

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FTC: Example #3 “Cold Away”

The various elements of the ad — the product name, the depictions of cold sufferers, and the reference to nose and throat health during the winter season — likely convey to consumers that the product helps prevent colds. Therefore, the advertiser must be able to substantiate

that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

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Substantiating claims

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/uc 0
0.htm

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Food Safety Modernization Act

Larisa Pavlick
VP, Global Regulatory & Compliance
United Natural Products Alliance

4Life
November 30, 2017

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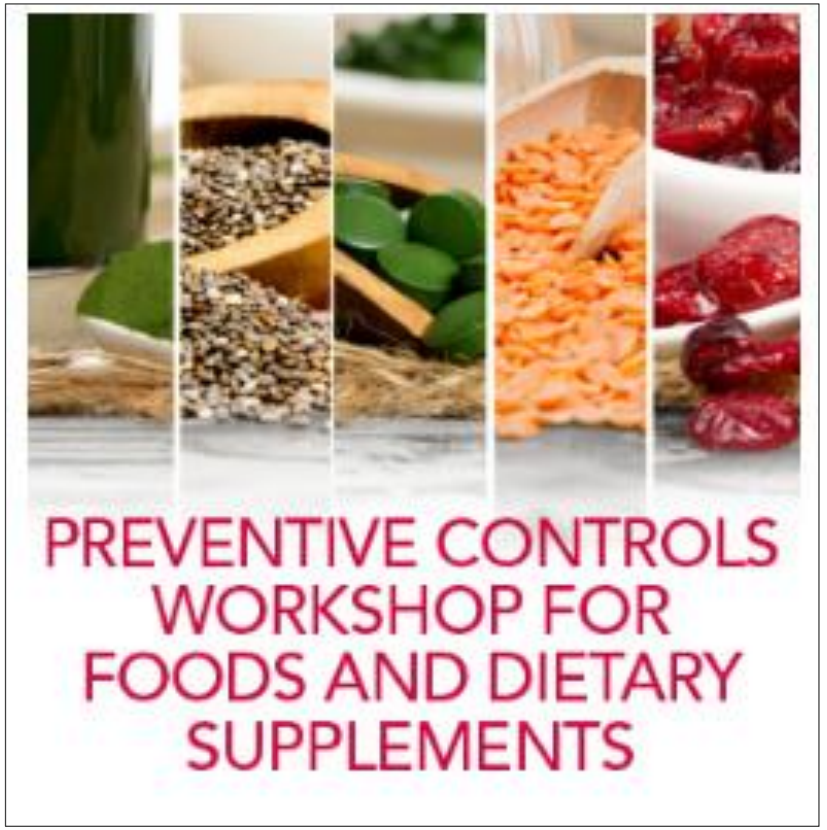
Pop Quiz

How many of you…

- Are familiar with the compliance requirements in FSMA-PCHF?
- Are you aware the compliance dates for the PCHF rule?
- Know what is a PCQI and the responsibilities?



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FSMA and the dietary supplement industry

Food Safety Modernization Act (FSMA)

- Preventive Controls for Human Food (PCHF)
  - ✓Preventive Controls Qualified Individual (PCQI)
- Foreign Supplier Verification Programs (FSVP)

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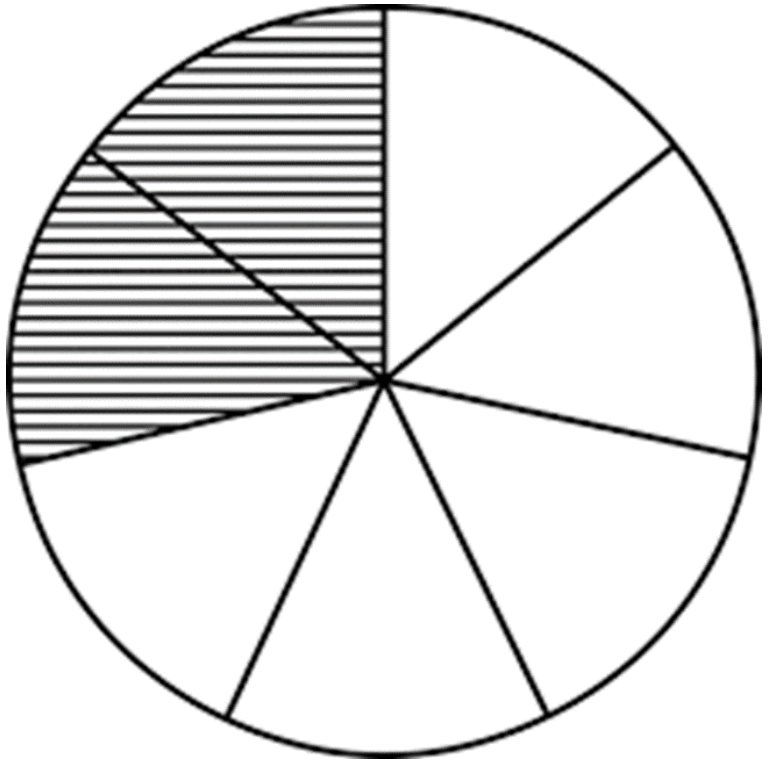
Largest misconception of our industry regarding FSMA-PCFH

Dietary Supplement exception

from Subparts C & G only



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FSMA = The new food regulations

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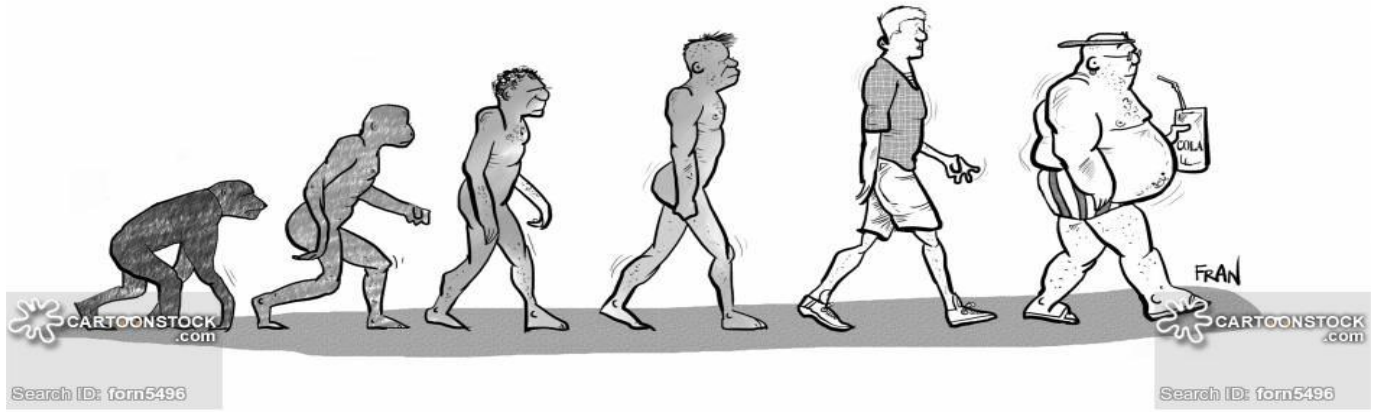
Food Safety Modernization Act (FSMA)

Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR Part 117)



- PCHF or PC
- Referred to as the Preventive Controls for Human Food regulation
- Signed into Law 2011 by President Obama

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FSMA: PCHF

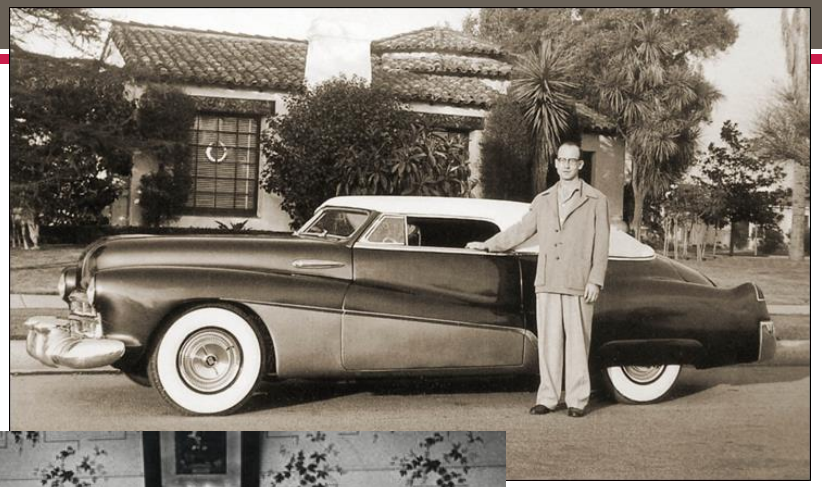
…is intended to ensure safe manufacturing/processing, packaging, and holding of food products for human consumption in the U.S.

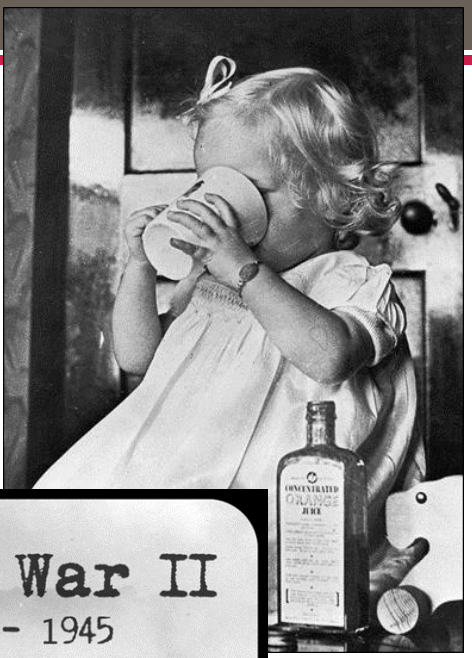
Compliance Dates:

- Large (>500 employees): September 2016
- Small (<500 employees): September 17, 2017
- Very small (<$1M/year): September 2018

Federal Food, Drug and Cosmetic Act, 1938

President Franklin D. Roosevelt
June 24, 1938





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FSMA: The evolution of modern food regulations

2009-2010 Foodborne Disease Outbreaks

- 9.4 million foodborne illnesses annually
- 1,527 outbreaks
  - 2009: 675
  - 2010: 852
- 29,494 illnesses
- 1,184 hospitalizations
- 23 deaths

Centers for Disease Control and Prevention
National Center for Health Statistics

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FSMA: The evolution of modern food regulations: Outbreak score card

Centers for Disease Control and Prevention
National Center for Health Statistics

	Outbreaks	Hospitalizations	Deaths
Norovirus	X (42%)	X (9%)	1
Salmonella	X (30%)	X (49%)	
E. Coli/E. Coli 0157	X	X (16%)	0157 = 4
Listeria		X	9
Clostridium botulinum		X	5
Clostridium perfringens			3
Shigella			1

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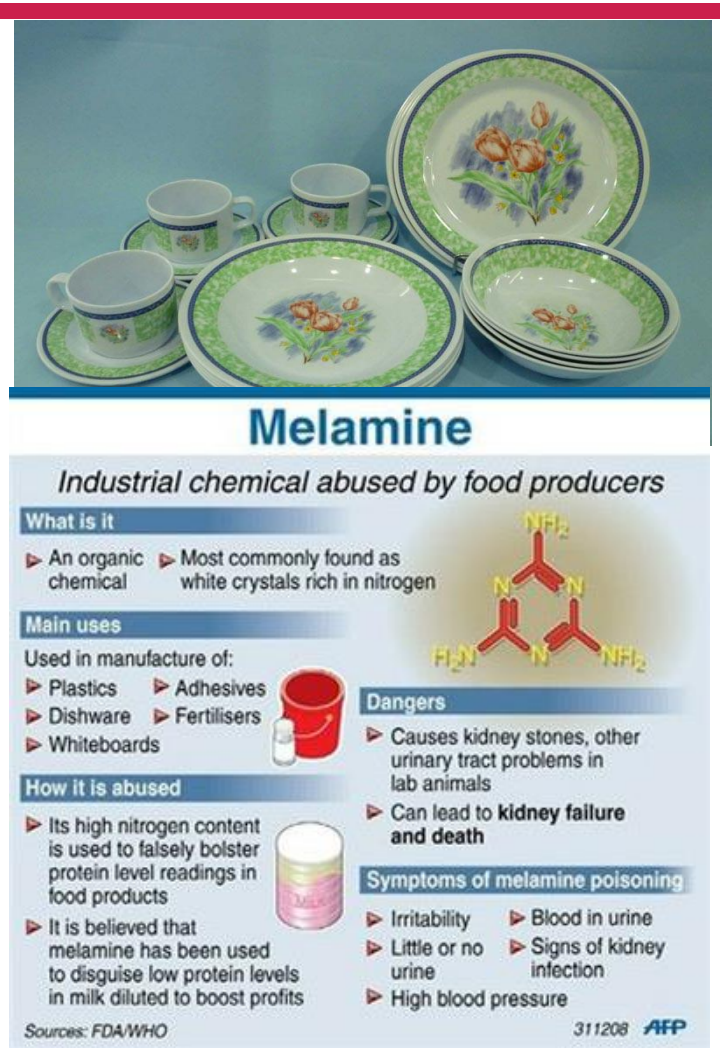
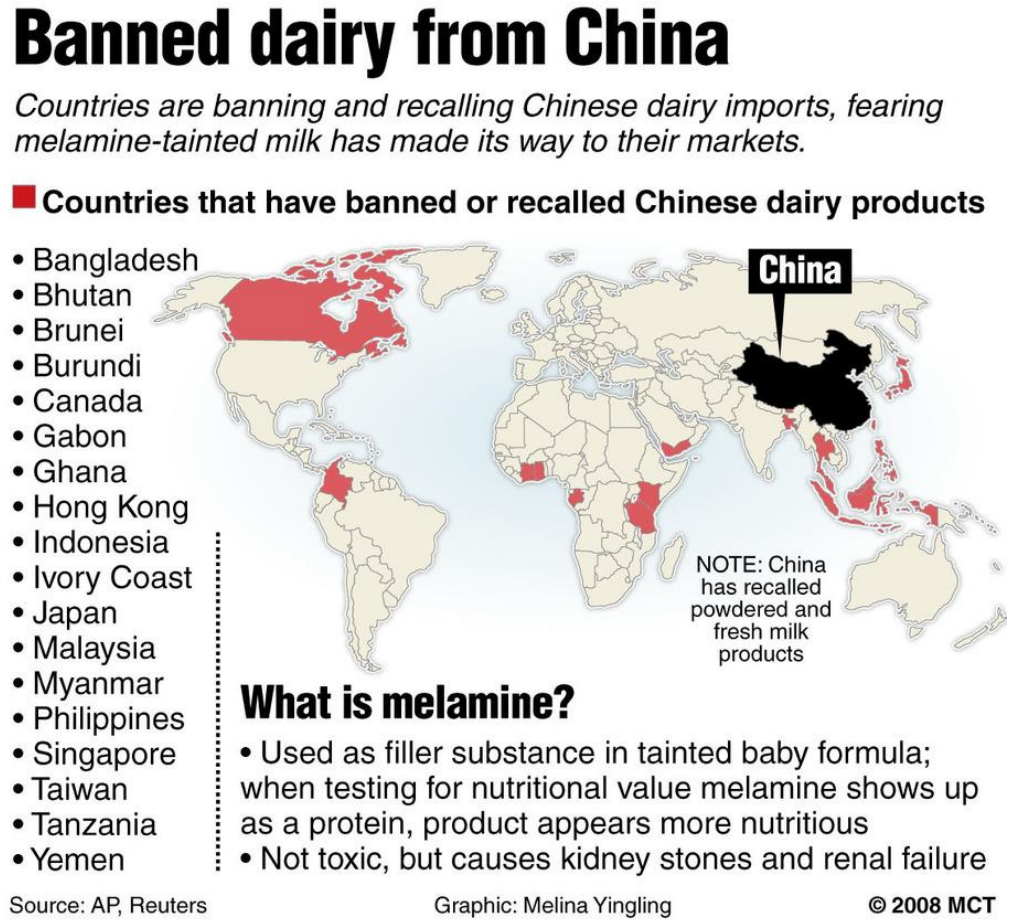
FSMA: The evolution of modern food regulations
Melamine recalls 2007-2009



"Since March 16, 2007, more than 150 brands of pet food have been voluntarily recalled by a number of companies."
— FDA



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Food Safety Modernization Act (FSMA)

Seven parts of FSMA, also known as foundational rules:

1. Preventive Controls for Human Food
2. Foreign Supply Verification Programs
3. Produce Safety Rule
4. Preventive Controls for Animal Food
5. Sanitary Transport of Human and Animal Food
6. Intentional Adulteration
7. Accredited Third Party Certification

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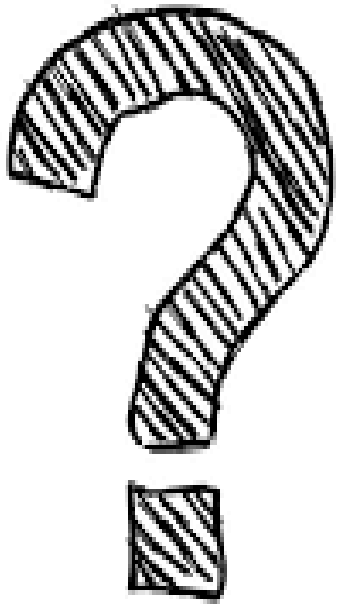
cGMP, Hazard Analysis and Risk-based Preventive Controls for Human Food (CFR Part 117)

- Subpart A: General
- Subpart B: Good Manufacturing Practice (GMP)
- Subpart C: Hazard analysis and risk-based Preventive Controls
- Subpart D: Modified Requirements
- Subpart E: Withdrawal of Qualified Facility
- Subpart F: Records
- Subpart G: Supply Chain Program

Food Safety Modernization Act and the dietary supplement industry



What does this mean to us?

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Applicability of FSMA for the DS industry

Raw materials and dietary ingredients

Nutrition Facts

Serving Size 125g

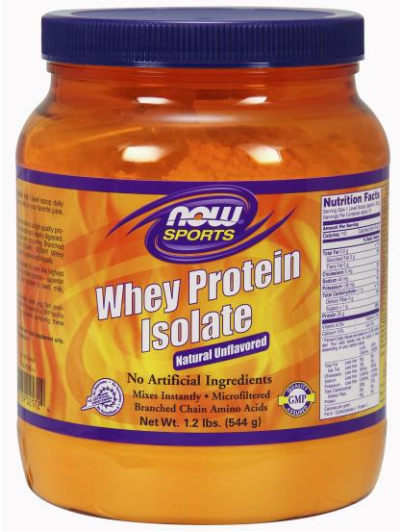
Amount Per Serving

Calories 65	Calories from Fat 2
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat	
Cholesterol 0mg	0%
Sodium 1mg	0%
Total Carbohydrate 17g	6%
Dietary Fiber 3g	12%
Sugars 13g	
Protein 0g	

Vitamin A	1%	• Vitamin C	10%
Calcium	1%	• Iron	1%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

NutritionData.com



For example:
Meal replacements, shakes, nutritional powders or greens

Also includes bars, gummies, drinks or any product marketed with a nutritional label

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Preventive Controls for Human Food (PCHF) dietary ingredients

DS.3 Are dietary ingredients exempt from the preventive controls for human food rule?

Reference:
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#DietarySupplements

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Food Safety Modernization Act: Preventive Controls for Human Food (PCHF)

No, DI are not exempt.

Dietary ingredients are subject to the requirements of the rule …

Including:

1. the current good manufacturing practice (CGMP) requirements of 21 CFR part 117, subpart B;
2. the hazard analysis and risk based preventive controls requirements of 21 CFR part 117, subpart C;
3. the supply chain program requirements of 21 CFR part 117, subpart G;
4. and the recordkeeping requirements of 21 CFR part 117, subpart F.

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Subpart C--Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 - Food safety plan.
§ 117.130 - Hazard analysis.
§ 117.135 - Preventive controls.
§ 117.136 - Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.
§ 117.137 - Provision of assurances required under 117.136(a)(2), (3), and (4).
§ 117.139 - Recall plan.
§ 117.140 - Preventive control management components.
§ 117.145 - Monitoring.
§ 117.150 - Corrective actions and corrections.
§ 117.155 - Verification.
§ 117.160 - Validation.
§ 117.165 - Verification of implementation and effectiveness.
§ 117.170 - Reanalysis.
§ 117.180 - Requirements applicable to a preventive controls qualified individual and a qualified auditor.
§ 117.190 - Implementation records required for this subpart.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117

Preventive Controls Qualified Individual (PCQI)

*"A qualified **individual who has successfully completed training** in the development and application of risk-based preventive controls at least equivalent to that received under a **standardized curriculum recognized as adequate by FDA** or is otherwise qualified through job experience to develop and apply a food safety system." -- 21 CFR Part 117.3*

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cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Responsibilities of the PCQI include overseeing or performing:

1. Preparation of the Food Safety Plan (FSP)
2. Validation of the preventive controls
3. Records review
4. Reanalysis of the Food Safety Plan, and other activities as appropriate for the food

21 CFR Part 117.180

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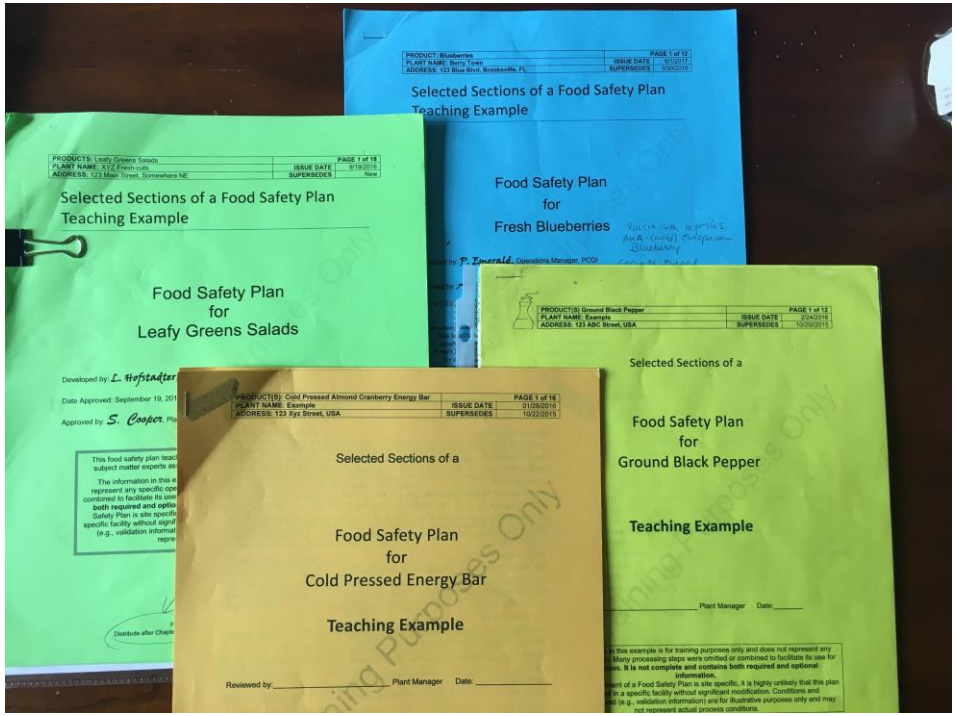
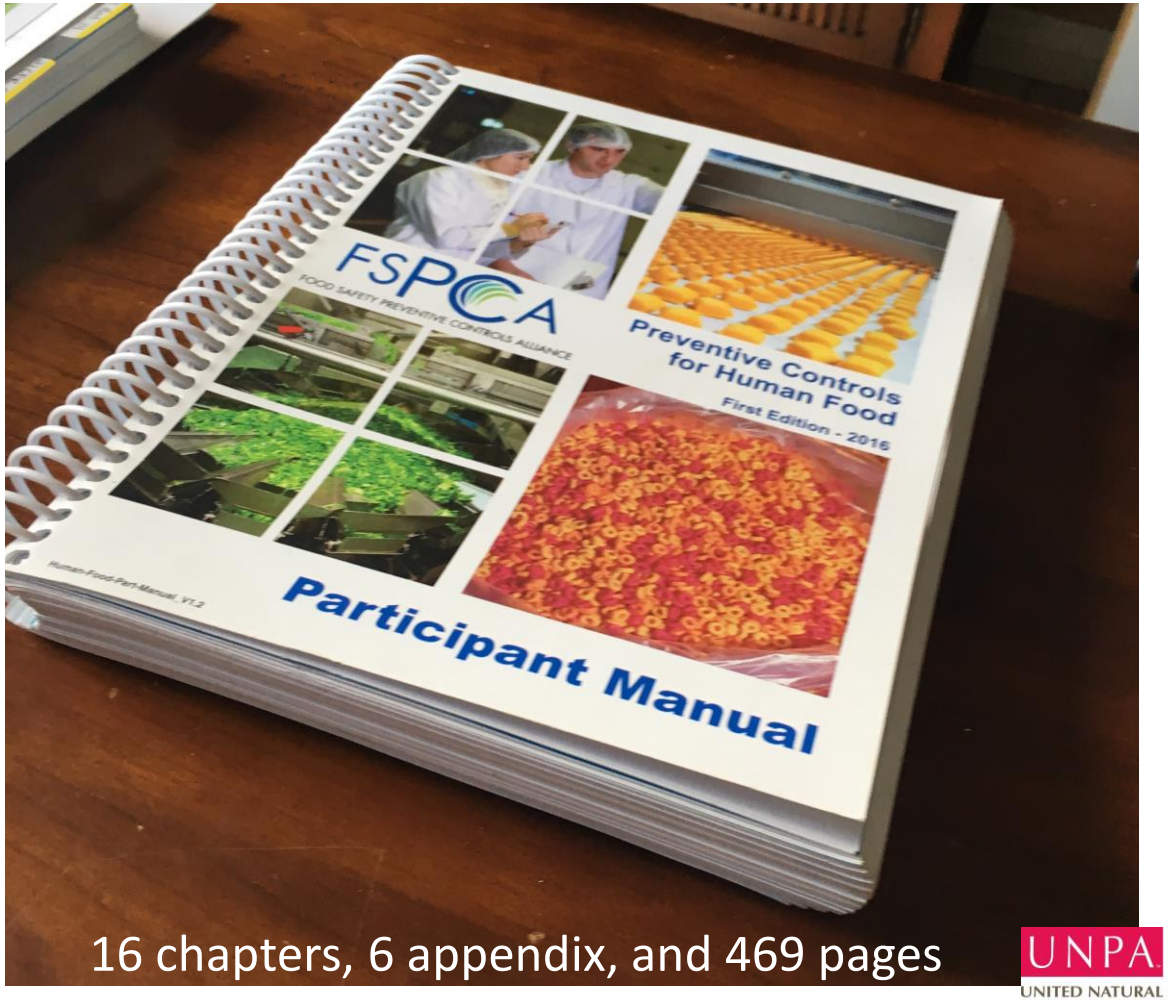
Preventive Controls Qualified Individual (PCQI)

“ …standardized curriculum recognized as adequate by FDA…”





16 chapters, 6 appendix, and 469 pages

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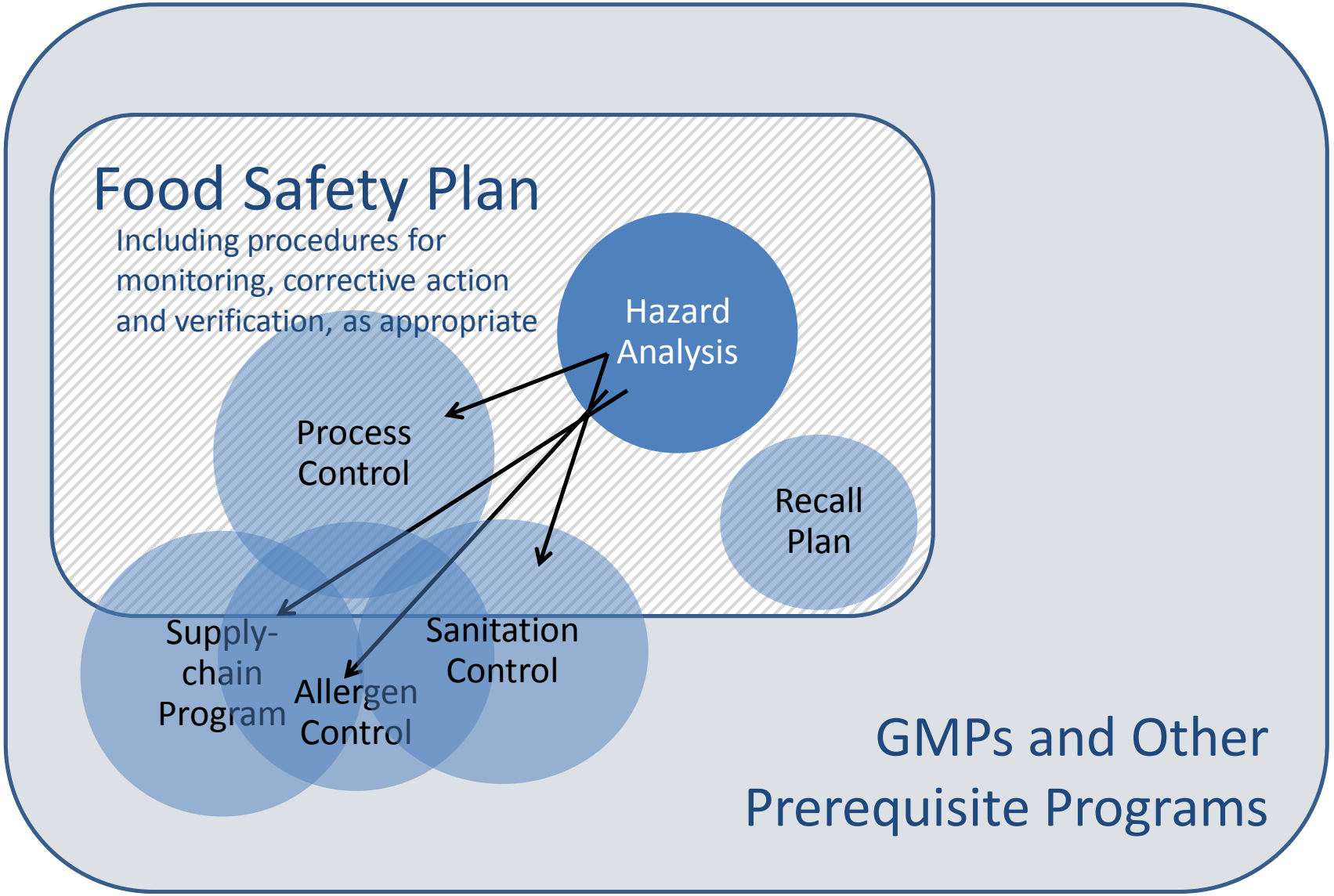
Preventive Food Safety Systems



From PCQI instructor slides

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DS manufacturer Preventive Controls for Human Food (PCHF)

“DS.1 Is a manufacturer of dietary supplements exempt from the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?”

Reference: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#DietarySupplements

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Food Safety Modernization Act
Preventive Controls for Human Food

"Dietary supplements are "food" as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act and is subject to the requirements related to preventive controls of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule, unless subject to an exemption. An exemption for dietary supplements is provided in 21 CFR section 117.5(e) which states that subparts C (hazard analysis and preventive controls requirements) and G (supply-chain program requirements) of 21 CFR part 117 do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of 21 CFR part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the FD&C Act (21 USC section 379aa-1) (Serious Adverse Event Reporting for Dietary Supplements)."

Source: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#Dietary Supplements

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Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF)

"Dietary supplements are "food" as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act)."

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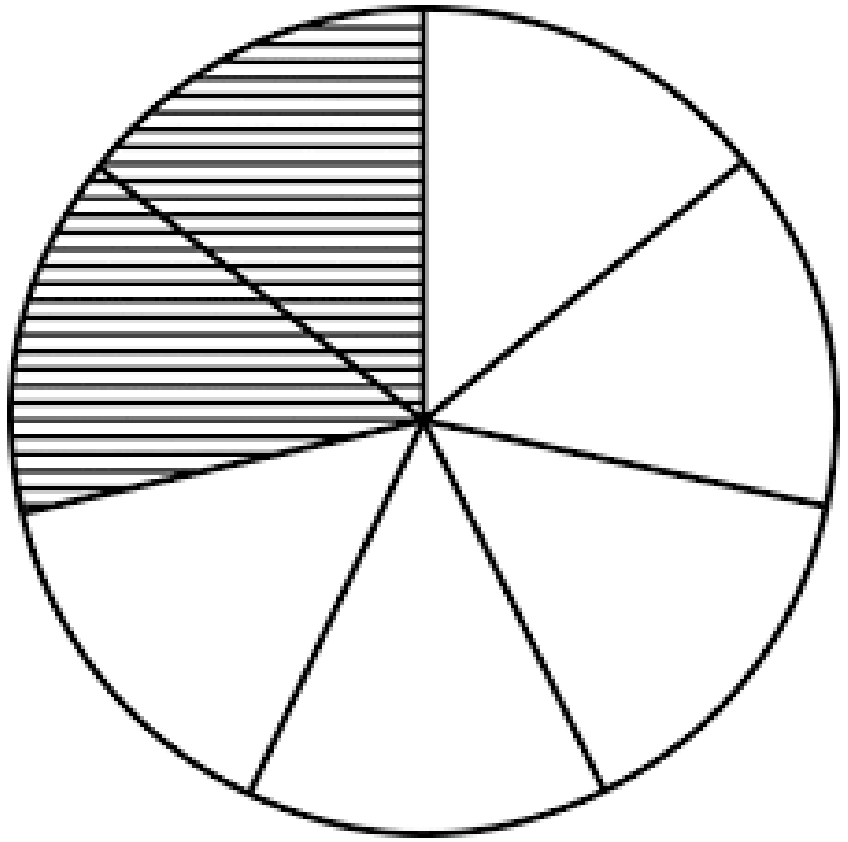
21 CFR Part 117 and applicability to DS industry

Dietary Supplement exception is **ONLY** for two of seven subparts!!



1. Subparts C (Hazard Analysis and Preventive Controls) and
2. Subpart G (Supply Chain Program)

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Largest misconception of our industry regarding FSMA-PCFH

if……in compliance with the requirements of

- 21 CFR part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) *and…*

- Serious Adverse Event Reporting for Dietary Supplements [Section 761 of the FD&C Act (21 USC section 379aa-1)]

21 CFR Part 117 and applicability to finished DS, MFG, warehouse or brand owner

Subpart A: General

Training requirements for employees engaged in MFG, processing, packaging, and holding food

1. **Qualified individual**
   - –Training, education, background, or experience to MFG, pack, or hold clean and safe food
2. **Receive training** in principles of food hygiene and food safety (employee health and hygiene), and assigned duties
   - ❑Record

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21 CFR Part 117 and applicability to DS industry

Subpart B: Good Manufacturing Practice (GMP)

Applies if the requirements in 117 are *above* those required by 21 CFR Part 111. Example: allergens

Changes from 21 CFR Part 110:

- Non-binding removed or made binding
- Allergen cross-contact text
- Training recommended in 110 is required in 117

cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Subpart B – Current Good Manufacturing Practice

- 117.10 Personnel
- 117.20 Plant and Grounds
- 117.35 Sanitary Operations
- 117.37 Sanitary Facilities and Controls
- 117.40 Equipment and Utensils
- 117.80 Processes and Controls
- 117.93 Warehousing and Distribution
- **117.95 Holding and distribution of food by-products for animal food**
- 117.110 Defect Action Levels

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Summary **FSMA-PCHF (21 CFR Part 117)**	**Dietary Ingredient and raw material suppliers**	**Companies selling finished dietary supplements**	**DS warehouse**	**DS MFG, contract MFG, and bulk MFG**
Subpart A: General	X	X	X	X
Subpart B: cGMP	X	If the expectations in 117 is above 111. Example: Allergens		
Subpart C: Hazard Analysis and Risk based Preventive Controls	X	No No FSP	No No FSP	No No FSP
Subpart D: Modified Requirements	X	X	X	X
Subpart E: Withdraw of a Qualified Facility	X	X	X	X
Subpart F: Records	X	X	X	X
Subpart G: Supply Chain Program	X	No	No	No
21 CFR Part 111	No	X	X	X
Serious Adverse Event Reporting for DS		Yes		Yes

Tan: by PCQI

Green: by Qualified Individual

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Regulatory and compliance update

Food Safety Modernization Act (FSMA)

- Preventive Controls for Human Food (PCHF)
  - ✓Preventive Controls Qualified Individual
- Foreign Supplier Verification Programs (FSVP)

Foreign Supplier Verification Programs

"The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards."

Who is controlling the hazard?

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

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Foreign Supplier Verification Programs

- Initial compliance date: May 30, 2017
- FSVP works in tandem with PCHF, except you must have a unique importer identification
- FSVP must be conducted by a “qualified individual”

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

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Regulatory and compliance update

Food Safety Modernization Act (FSMA)

- Preventive Controls for Human Food (PCHF)
  - ✓Preventive Controls Qualified Individual
- Foreign Supplier Verification Programs (FSVP)

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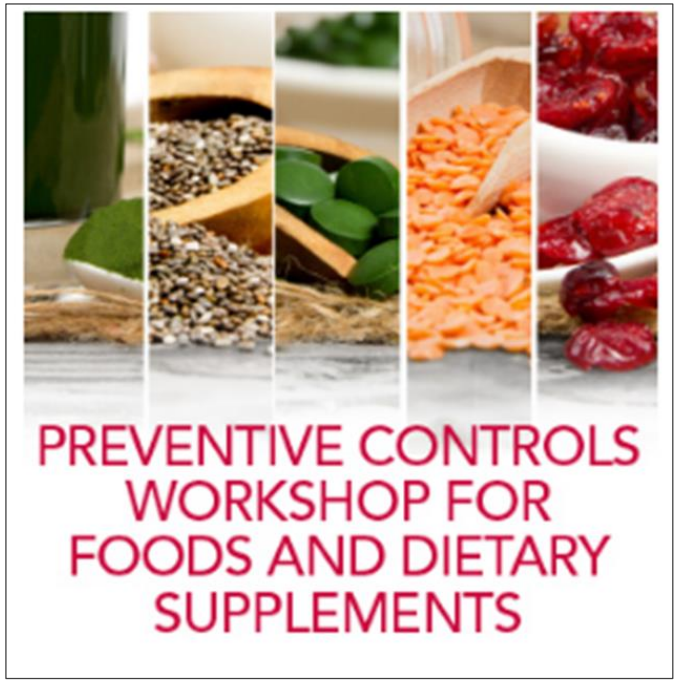
What should you do next?

- **Become familiar with the new FSMA regulations**
  - –Preventive Controls for Human Food (PCHF)
  - –Foreign Supplier Verification Program (FSVP)
- **Obtain training for staff at all levels**



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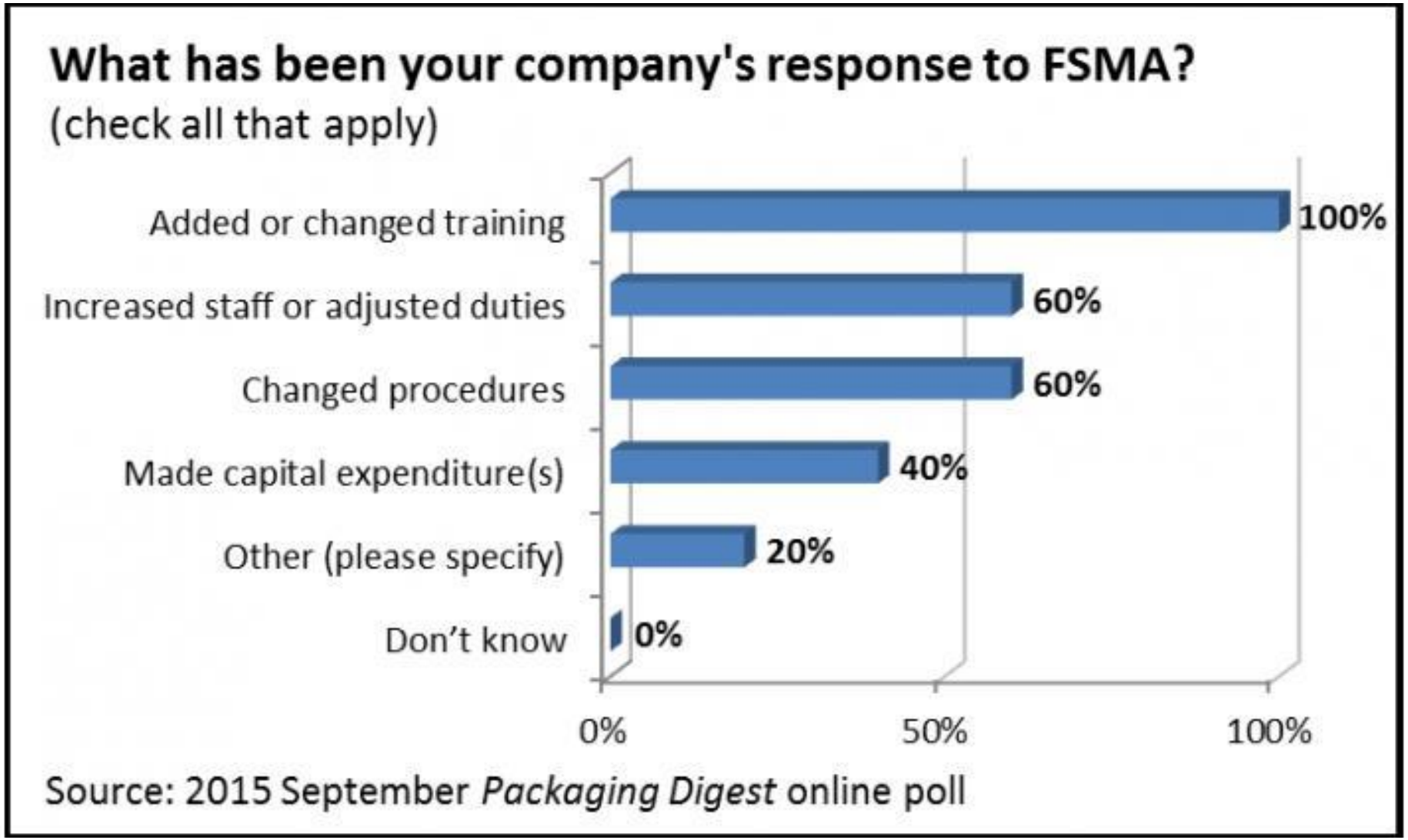
What should you do next?



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UNPA education & training

UNPA now offers a wide range of public and *onsite* trainings:

- Current Good Manufacturing Practices (cGMP)
- Food Safety Modernization Act (FSMA)
  - ✓PCHF including Preventive Controls Qualified Individual (PCQI)
  - ✓Foreign Supplier Verification Programs (FSVP)

… and a host of other education and training offerings.

For more information, contact us!

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Summary

UNPA™

UNITED NATURAL PRODUCTS ALLIANCE®

Claims

- FDA
- FTC
- Substantiation

Food Safety Modernization Act (FSMA)

- Preventive Controls for Human Food (PCHF)
  - ✓Preventive Controls Qualified Individual (PCQI)
- Foreign Supplier Verification Programs (FSVP)

Questions?

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Thank you!

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