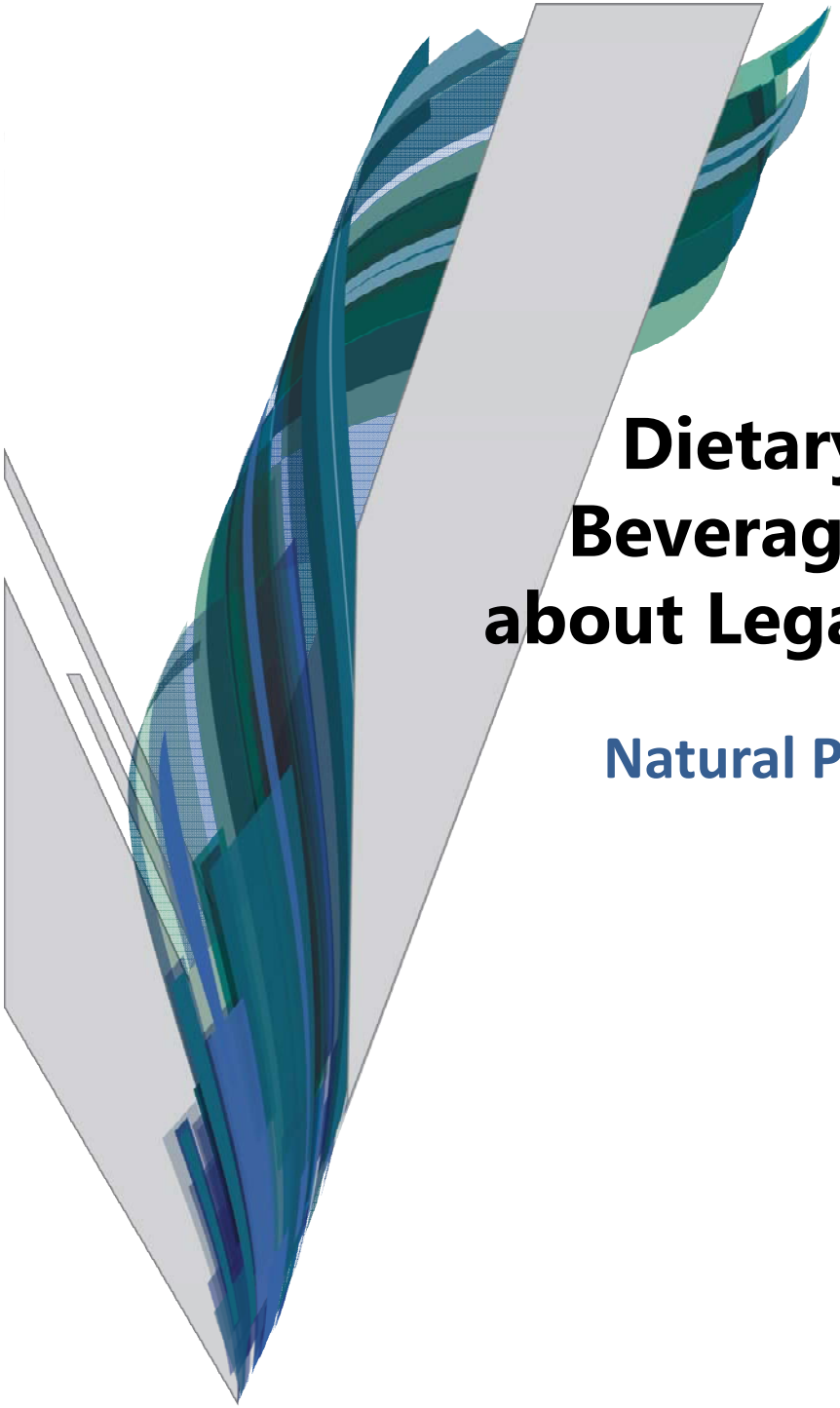

VENABLE

Dietary Supplements, Food, and Beverage: What You Need to Know about Legal and Regulatory Compliance

Natural Products Expo West/Engredea 2017

Marriott Anaheim

Marquis Ballroom Northwest

Saturday, March 11, 2017

3:00 pm – 6:00 pm PST

What You Need to Know about State Attorney General and County District Attorney Investigations

Session Speakers:

Todd Harrison, Esq.
Partner and Co-Chair, Food and Drug Law, Venable LLP

Tracy Hughes, Esq.
Deputy District Attorney, Consumer Protection Unit, Orange County District Attorney's Office

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State Attorneys General

- State AG has very broad consumer protection authority
- Enforcement authority is derived from Unfair and Deceptive Acts and Practices Statutes (UDAP)
  - Prohibition of "unfair and deceptive acts"
  - Scope of authority varies by state
- Authority is similar to that of the FTC
- Tools
  - Restitution
  - Civil penalties
  - Injunctions

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"Power" of State Attorneys General

- Bully Pulpit—Can Bring Attention to Issues
  - Press
  - Advocacy groups
- Reports and Letters
- Pressure on Companies
  - Influence Washington
  - Weigh in on federal rulemaking
  - Request federal authorities to investigate
  - Testify in Congress

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New York Attorney General Actions

- February 2, 2015: NYAG Schneiderman accused major retailers of selling fraudulent and potentially dangerous store-brand herbal supplements
- Demanded the retailers remove the products from stores:
  - GNC
  - Target
  - Walmart
  - Walgreens

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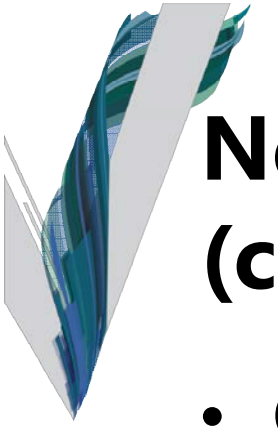

New York Attorney General Actions (cont.)

- On September 9, 2015, Attorney General Schneiderman issued cease-and-desist letters to 13 makers of Devil's Claw supplements
- Allegedly used DNA testing and claimed the supplements contained a cheaper related species
- Based on DNA barcode analysis conducted by the New York Botanical Garden

DNA Test Results

- 21% of the test results from store-brand herbal supplements verified DNA from the plants listed on the products' labels
  - 79% did not contain DNA related to the labeled content
- DNA bar coding used to test
  - Criticized by experts and the industry because DNA is destroyed during the manufacturing and extraction process for herbal supplements
  - "It's no surprise that they didn't find DNA of the original plant in the supplements." – Pieter Cohen, Harvard Medical School

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NY AG Supplement Sweep: Update

- **September 9, 2015:** Nature's Way committed to continue efforts to employ DNA barcode testing across "Green" and "Purple" herbal lines. Devil's Claw products will contain *Harpagophytum procumbens* only, and not *Harpagophytum zeyheri.*
  - Did not receive cease-and-desist letter.

- **March 30, 2015:** GNC agreed to implement DNA barcoding on "active" plant ingredients and testing for allergen contamination, and to post signs advising consumers of the processed chemicals.

- **September 20, 2016:** NBTY (manufacturer of Walgreens and Walmart supplements) agreed to implement DNA barcoding over the next 2 years. After 2 years, NBTY will test all herbal ingredients with a scientifically reliable barcode.

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Prevagen Complaint

- January 9, 2017: FTC and NY AG filed a complaint against the marketers of Prevagen
  - Prevagen contains the active ingredient apoaequorin, a dietary protein originally derived from a species of jellyfish living in Puget Sound
  - According to Prevagen's marketers, this dietary protein can help reduce common memory problems
  - In substantiating these claims, defendants relied on a double-blind, placebo-controlled human clinical study called the Madison Memory Study

Prevagen Complaint

- The complaint alleges that the defendants violated the FTC Act and New York law by making false and unsubstantiated claims that Prevagen improves memory, offers other cognitive benefits, and is "clinically shown" to work

- FTC and NY AG allege that the Madison Memory Study failed to reveal a statistically significant improvement for the Prevagen group

- The complaint requests, among other relief, a permanent injunction, consumer refunds, and civil penalties of up to $5,000 for each violation of New York law

False Advertising: State Enforcement

- AGs have broad power to prevent consumer deception
- AGs do not hesitate to use this power in an array of industries, including food, drugs, and dietary supplements
- **Sept. 13, 2016:** Iowa AG announced a settlement against dietary supplement manufacturer for deceptive "bladder control" claims. Company is required to pay $30,000 and cease marketing the product in the state of Iowa.

FlexiPrin and CogniPrin Complaint

- February 22, 2017: FTC and Maine AG filed a complaint against three supplement-marketing corporations
  - Defendants distributed and sold FlexiPrin for joint health and CogniPrin for memory improvement

- Complaint alleges that
  - Defendants made false claims about the efficacy and testing of their products; and
  - Deceptively enrolled consumers in "continuity plans"

Congressional Inquiry

- April 2, 2015: 14 AGs asked Congress to launch an investigation of dietary supplements
  - FDA should evaluate adequacy and effectiveness of existing quality assurance measures
  - FDA should develop standards and restrictions governing the use of the terms “natural,” “herbal,” and “extract”
  - FDA should develop enhanced, uniform, industry-wide quality assurance and verification regimes to guarantee the source, identity, purity, and potency of materials incorporated into herbal and dietary supplements
  - FDA should develop enhanced manufacturing and supply-chain management requirements for the industry to guarantee the safety and efficacy of herbal and dietary supplements

California DA's Nutritional Supplement Task Force

- Proposition 64 (2004): Limited private enforcement of unfair business competition laws to individuals who actually suffer a financial loss as a result of unfair business practices

- *Kwikset Corp. v. Superior Court* (Jan. 27, 2011)
  - Kwikset sold locks labeled "Made in the U.S.A." that contained foreign parts
  - Supreme Court of CA held that plaintiffs who allege they were deceived by a product's label into purchasing a product that they would not have purchased otherwise have "lost money or property" as required by California Proposition 64 and have standing to sue under the UCL and false advertising law. The court emphasized: "labels matter."

California DA's Nutritional Supplement Task Force (con't)

- District Attorney Office keeps money from settlements, which can be a substantial amount
  - E.g., $1,796,114.50 (deceptive advertising of AbGone Dietary Aid)
  - E.g., $905,000 (deceptive advertising of the Sensa "sprinkle diet" product)

- Hot topics for the Supplement Task Force:
  - Proposition 65
  - Elder fraud
  - Auto renewals
  - Online sales
  - Illegal products
  - Substantiation

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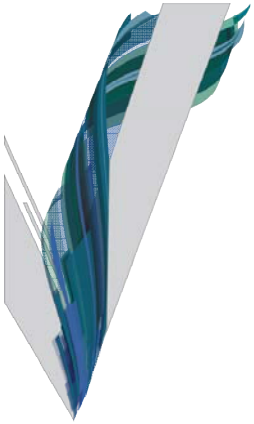

Break

Latest Developments at the FDA and FTC: How Will They Affect Your Business?

Session Speakers:

Michelle Jackson, Esq.
Partner,
Food and Drug Law,
Venable LLP

Kristen Klesh, Esq.
Associate,
Food and Drug Law,
Venable LLP

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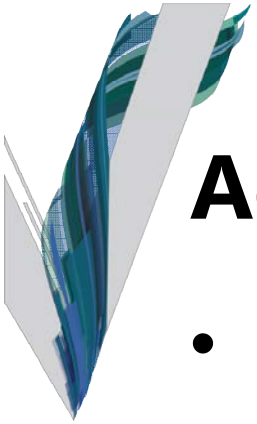

Agenda

- Recent Developments at the FDA
  - New FDA Nutrition Labeling Rules
    - Supplement Facts Panel Changes
    - Nutrition Facts Panel Changes
  - FDA Enforcement Trends
    - Ingredient Issues
    - GMP Issues
  - Other recent developments at the FDA

- Recent Developments at the FTC

New FDA Nutrition Labeling Rules

1. "Food Labeling: Revision of the Nutrition and Supplement Facts Labels"
   - Published: May 27, 2016

2. "Food Labeling: Serving Sizes of Foods that Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments"
   - Published: May 27, 2016

New FDA Nutrition Labeling Rules (cont'd)

- Overview of Changes:
  - Ingredient declarations (required declarations, ingredient names, units of measure, nutrient definitions)
  - Changes to DRVs/ RDIs
  - Changes to nutrition panel formatting

- Compliance Date:
  - July 26, 2018 – for companies with over $10 million in annual sales
  - July 26, 2019 – for companies with less than $10 million in annual sales

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Ingredient Declaration: Added Sugars

- Added Sugars *must* be declared if present at more than 1g per serving
  - Or even if less than 1 g/serving if claims are made about sweeteners, sugars, added sugars, or sugar alcohol content

- "Added Sugars" includes:
  - Sugars (free, mono- and disaccharides)
  - Sugars from syrups and honey
  - Sugars from concentrated fruit or vegetable juices in excess of what would be expected from the same volume of 100 percent juice of the same type
    - Limited exceptions

Ingredient Declaration: Added Sugars

Old Version

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

New Version

Supplement Facts

Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

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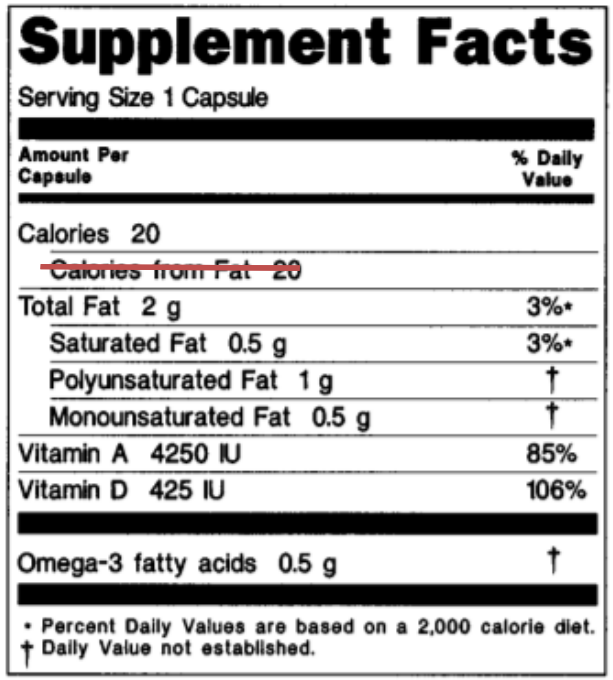
Ingredient Declarations: Calories and Carbs

- "Calories from fat" no longer required to be declared on the label
- "Other carbohydrates" no longer permitted to be declared on the label



Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	% Daily Value
Calories 20	
~~Calories from Fat 20~~	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

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Ingredient Declarations: Vitamins A, C, D, and Potassium

- Vitamin D and potassium are now required declarations
  - Vitamin D and potassium must be declared when they are present in a dietary supplement in amounts that exceed what can be declared as zero
  - Vitamin D must now be declared in micrograms (IUs permitted, as well, but voluntary)

- Vitamin A and C declarations are now voluntary, unless:
  - Added to the product for purposes of supplementation; or
  - A claim is made about them

Ingredient Declarations: Choline and Fluoride

- Choline must now be declared when added to the product for purposes of supplementation, or when a claim is made about it (otherwise voluntary/permitted).
  - For dietary supplements, choline shall follow pantothenic acid.

- Fluoride must be declared when a claim is made about it (otherwise voluntary/permitted).
  - For dietary supplements, fluoride shall follow potassium.
  - Please note that there was NO RDI established for fluoride.

Ingredient Declarations: Folic Acid and Folate

- Folate must now be declared in mcg Dietary Folate Equivalents (DFE) and must be declared using the name "folate."
  - Conversion of naturally-occurring folate and folic acid to DFE: **1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg of folic acid (from fortified food or added to a dietary supplement).**
  - The declaration of folate must include a percent DV based on mcg DFE.
- "Folacin" is no longer a permitted synonym that may be used to declare folic acid on the Supplement Facts label.

Ingredient Declarations: Folic Acid and Folate (cont'd)

- Dietary supplement-specific requirement:
  - If folic acid is added to the product or if a claim is made about the nutrient, the mcg of folic acid must be stated in parentheses following the declaration of folate. E.g., "Folate 400 mcg DFE (240 mcg folic acid)."

- When a mixture of folate and folic acid is present in a food or supplement, written records must be kept to demonstrate content of each

Ingredient Declarations: Vitamin A

- Vitamin A should no longer be declared in IUs; rather it should be declared in mcg Retinol Activity Equivalents (RAE).
- Conversions of forms of vitamin A to mcg RAE: **1 retinol activity equivalent (mcg RAE) = 1 mcg retinol; 2 mcg supplemental β-carotene; 12 mcg of dietary β-carotene; 24 mcg of other dietary provitamin A carotenoids (α-carotene or β-cryptoxanthin).**
- New dietary supplement-specific requirement:
  - When the percentage of the vitamin A that is β-carotene is stated in parentheses following the declaration of vitamin A, it should be declared using "mcg" (representing mcg RAE) (e.g., "Vitamin A (90% (810 mcg) as beta-carotene)").

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Ingredient Declarations: Vitamin E

- Vitamin E must now be declared as mg alpha-tocopherol (α-tocopherol). More specifically, it must be declared as the four 2R stereoisomeric forms (RRR, RSR, RRS, and RSS) of α-tocopherol (the natural stereoisomers).
- Conversion: **1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR-α-tocopherol = 2 mg *all rac*-α-tocopherol.**
  - The *all rac*-α-tocopherol acetate in fortified foods or dietary supplements has one-half the activity of RRR-α-tocopherol naturally found in foods or the 2R stereoisomeric forms of α-tocopherol.

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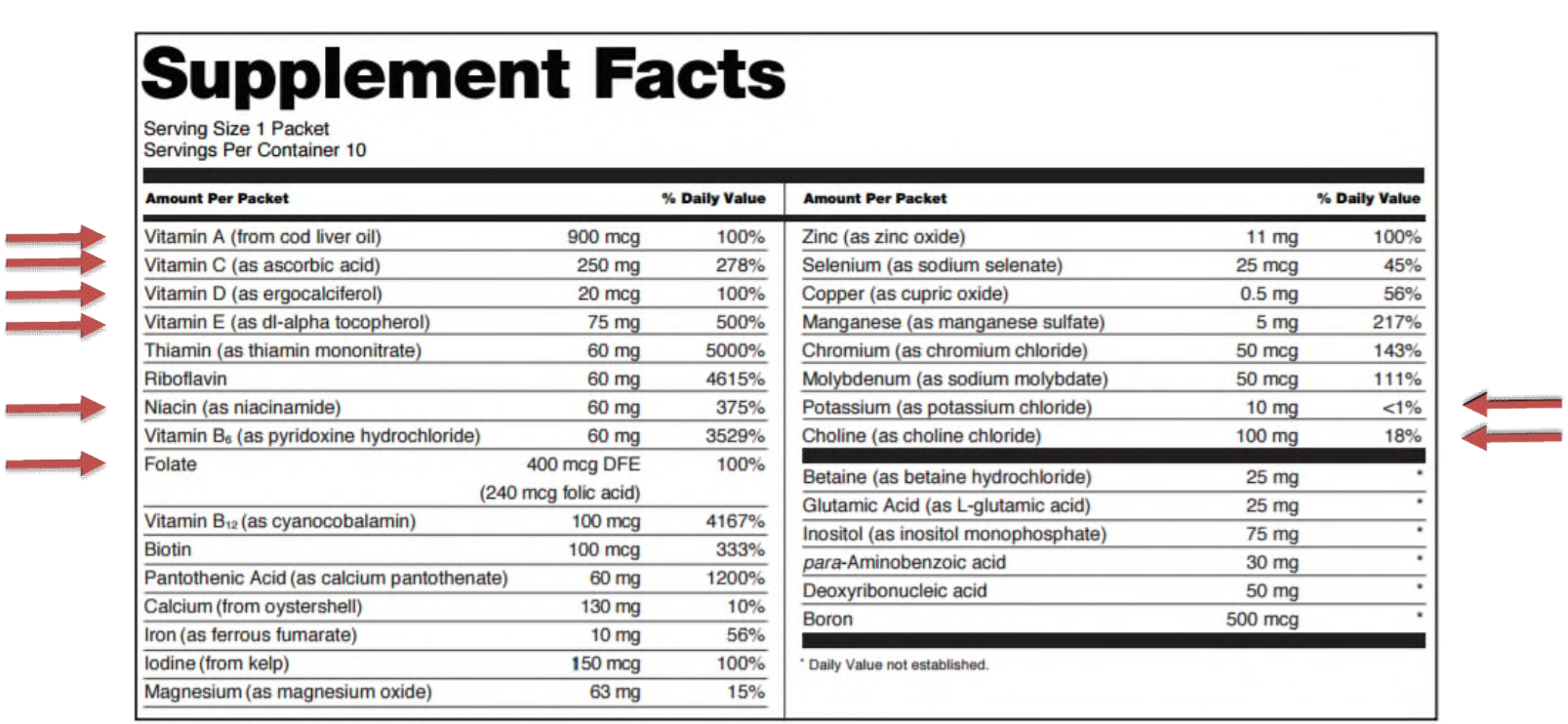
Ingredient Declarations: Vitamin E (cont'd)

- The ester forms of natural and synthetic vitamin E (*e.g.,* d-α-tocopheryl acetate and α-tocopheryl succinate) are considered as α-tocopherol forms of vitamin E
- Other forms of vitamin E (*e.g.,* gamma-tocopherol, delta-tocopherol, tocotrienols) may not be included in the declaration but may be declared in the ingredient list or as dietary ingredients in dietary supplements
- When a food or supplement product contains both RRR-α-tocopherol and all rac-α-tocopherol, manufacturers (and presumably private-label distributors) must make and keep written records

Ingredient Declarations: Niacin

- The new RDI for niacin is expressed as niacin equivalents (NE) because the body's niacin requirement is met not only by preformed niacin (nicotinamide, nicotinic acid, and its derivatives) in the diet, but also from conversion from dietary protein containing tryptophan
- While the unit of measurement for the RDI for niacin is listed as mg NE in 21 C.F.R. § 101.9(c)(8)(iv), only "mg" will continue to be declared on nutrition and supplement facts labeling
- Niacin equivalents (NE) shall be calculated as follows: **1 mg NE = 1 mg niacin = 60 mg tryptophan**

Ingredient Declarations



Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	900 mcg	100%
Vitamin C (as ascorbic acid)	250 mg	278%
Vitamin D (as ergocalciferol)	20 mcg	100%
Vitamin E (as dl-alpha tocopherol)	75 mg	500%
Thiamin (as thiamin mononitrate)	60 mg	5000%
Riboflavin	60 mg	4615%
Niacin (as niacinamide)	60 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	60 mg	3529%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	4167%
Biotin	100 mcg	333%
Pantothenic Acid (as calcium pantothenate)	60 mg	1200%
Calcium (from oystershell)	130 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium oxide)	63 mg	15%

Amount Per Packet		% Daily Value
Zinc (as zinc oxide)	11 mg	100%
Selenium (as sodium selenate)	25 mcg	45%
Copper (as cupric oxide)	0.5 mg	56%
Manganese (as manganese sulfate)	5 mg	217%
Chromium (as chromium chloride)	50 mcg	143%
Molybdenum (as sodium molybdate)	50 mcg	111%
Potassium (as potassium chloride)	10 mg	<1%
Choline (as choline chloride)	100 mg	18%
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established.

Other ingredients: Cellulose, stearic acid, and silica.

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Ingredient Declarations: Dietary Fiber

- The final rule defines dietary fiber as follows:
  - Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are *intrinsic and intact in plants*; and isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

- If a dietary fiber is an isolated or synthetic non-digestible carbohydrate, it may *only* be included in the dietary fiber declaration if FDA includes the fiber on a list the agency has created.

Ingredient Declarations: Dietary Fiber

- FDA's current list of isolated or synthetic non-digestible carbohydrates that may be declared as fiber:
  - β-glucan soluble fiber (as described in 21 C.F.R. § 101.81(c)(2)(ii)(A));
  - psyllium husk (as described in 21 C.F.R. § 101.81(c)(2)(ii)(A)(6));
  - cellulose;
  - guar gum;
  - pectin;
  - locust bean gum; and
  - hydroxypropylmethylcellulose (HPMC).
- The list does *not* include inulin and other plant fibers

Changes to DRVs

- Increased the DRV for total fat to 78 grams
- Increased the DRV for dietary fiber from 25 grams to 28 grams
- Decreased the DRV for total carbohydrate to 275 grams
- Decreased the DRV for sodium from 2,400 mg to 2,300 mg
- Established DRV for added sugars of 50 grams
- Included RDIs/DRVs for infants, children, and pregnant women in the new rules

New RDIs

Nutrient	Unit of measure	RDI			
		Adults and children ≥4 years	Infants [1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin A	Micrograms RAE [2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg) [3]	20	10	15	15
Vitamin E	Milligrams (mg) [4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE [5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate [6]	Micrograms DFE [7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8] 71

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Changes to Nutrition Facts Panel: Formatting

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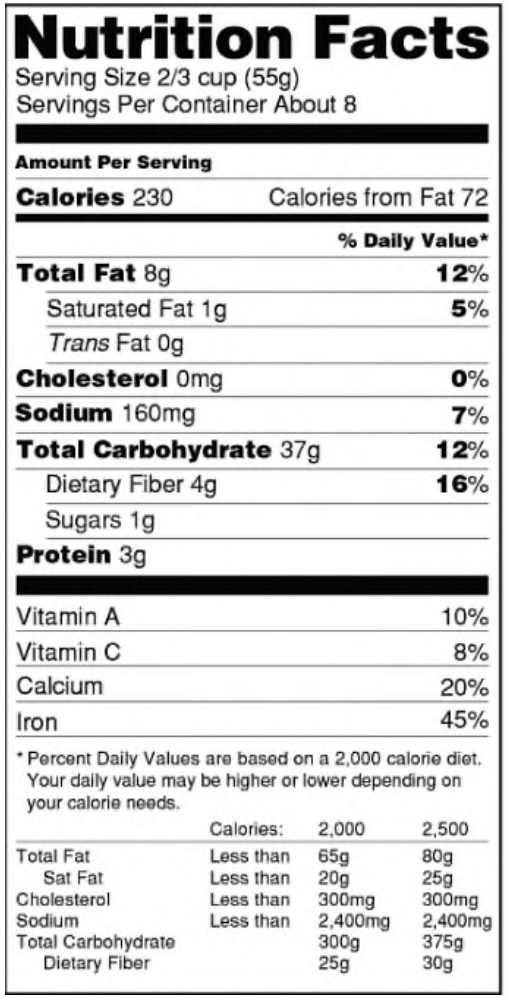
Changes to Nutrition Facts Panel: Formatting (cont'd)

Old Version



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

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

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

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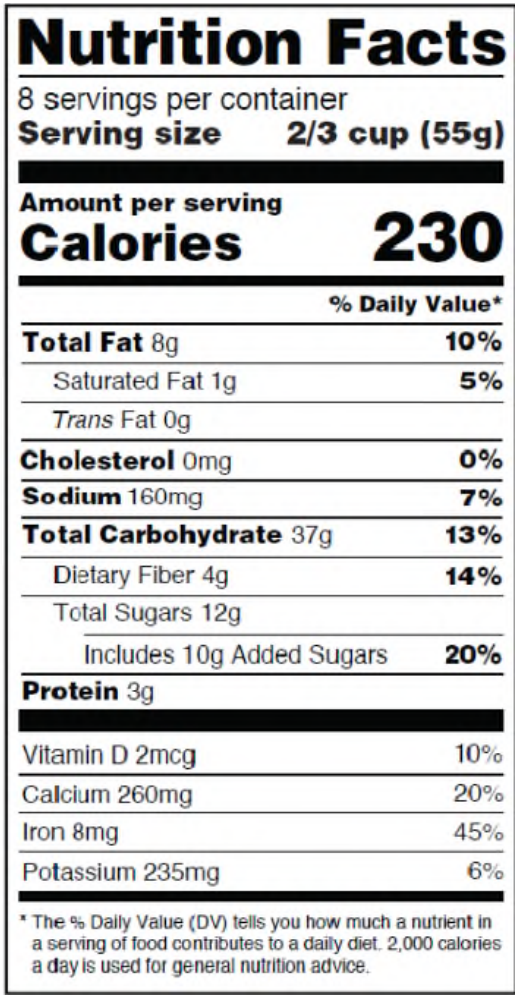

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

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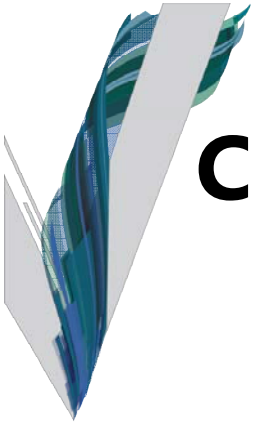
New Serving Size Rules

- To address containers that may be consumed in a single-eating occasion,
- All containers with less than 200 percent of the RACC must be labeled as a single-serving container
- Containers and units that contain at least 200 percent and up to and including 300 percent of the RACC must be labeled with an additional column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (*i.e.,* the serving size derived from the RACC).
- RACCs changed for certain food types

Changes to Nutrition Facts Panel



Nutrition Facts

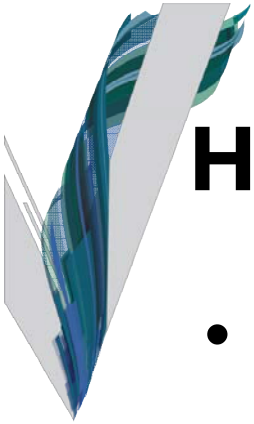
2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

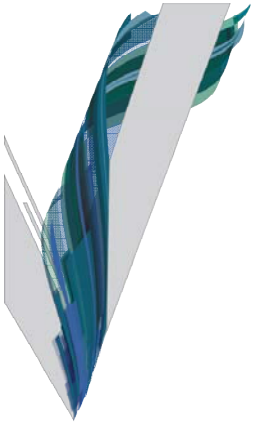
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

VENABLE



How Will This Affect Your Business?

- Likely need to relabel many products
- Need to gain additional information from manufacturers or suppliers (*e.g.,* raw material records)
- If you have a large number of products, likely need to begin this process now



FDA Enforcement Trends: Ingredient-Specific Issues

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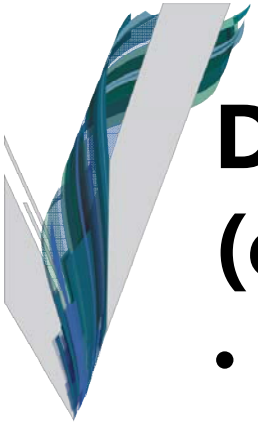
Definition of Dietary Supplement

- Under the Federal Food, Drug, and Cosmetic Act, a dietary ingredient is defined to mean:
  1. A vitamin;
  2. Mineral;
  3. Herb or other botanical;
  4. Amino acid;
  5. Dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
  6. A concentrate, metabolite, constituent, extract, or combination of the preceding substances.

  (with some exceptions)

Ingredients Prohibited from Use in Supplements

- Methylsynephrine
  - April 2016: FDA issued 7 Warning Letters about 8 products containing this ingredient.
  - Methylsynephrine, also known as oxilofrine and p-hydroxyephedrine, "does not meet the statutory definition of a dietary ingredient" and any product that declares this ingredient is misbranded.



Definition of Dietary Supplement (cont'd)

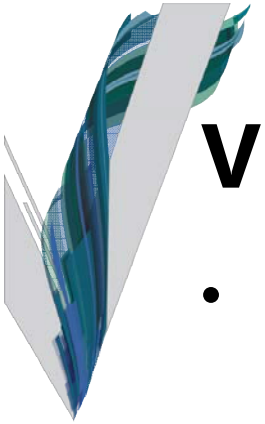
- The term "dietary supplement" does NOT include:
  i. An article that is approved as a new drug, certified as an antibiotic, or licensed as a biologic, or
  ii. An article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public

- Which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food
- *Unless* the FDA has issued a regulation permitting sale of the ingredient in dietary supplements

Cannabidiol (CBD)

- February 2016: 8 Warning Letters about 22 products citing misbranding violations for claims that established the products as new drugs (*i.e.*, disease claims).

- ***The Letters also noted that CBD products cannot be marketed as a dietary supplements because they are excluded from the of a dietary supplement because an IND has gone into effect.***



Vinpocetine

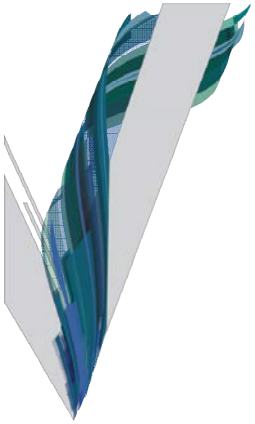
- September 2016: FDA published a *Federal Register* notice with agency's tentative conclusion that Vinpocetine (1) does not meet the definition of a dietary ingredient and (2) is excluded from the definition of a dietary supplement" because it was not marketed as a food or supplement before it was tested as a drug
- FDA's position that it therefore may NOT be used as an ingredient in dietary supplements
- FDA requested comments from industry
- Vinpocetine is also known as:
  - Ethyl Apovincaminate
  - Common Periwinkle Vinpocetine
  - Lesser Periwinkle extract
  - *Vinca minor* extract

New Dietary Ingredients (NDIs)

- For dietary ingredients (in dietary supplements) that were not marketed prior to October 15, 1994 (known as new dietary ingredients (NDIs)):
  - You must submit an NDI notification to the FDA, at least 75 days before introducing the dietary ingredient or dietary supplement into interstate commerce, demonstrating a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe
  - *Unless* the dietary ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered

FDA Warning Letters re: NDIs

- *Acacia rigidula* (*A. rigidula*)
  - March 2016: 6 Warning Letters about 6 products containing *A. rigidula*, which is also known as Vachellia rigidula, Chaparro Prieto, and blackbrush.
  - Per FDA, *A. rigidula* cannot be lawfully marketed as a dietary supplement ingredient because it is an NDI, and to be lawfully marketed, *A. rigidula* must meet the two requirements under 402(f) of the FD&C Act.



FDA Enforcement Trends: GMP Violations

Highlights of Recent FDA Inspections: Form 483 Observations

- Most frequently observed violations during manufacturer and private label distributor (PLD) facility inspections include:
  - 21 CFR 111.70(e): Failure to establish product specification for the identity, purity, strength, or composition of the finished dietary supplement **(69)**
  - 21 CFR 111.75(a)(1)(i): Failure to conduct at least one appropriate test or examination to verify the identity of a dietary supplement ingredient prior to its use **(50)**
  - 21 CFR 111.205(a): Failure to prepare or follow a written master manufacturing record for each batch size of a dietary supplement that you manufactured **(44)**
  - 21 CFR 111.75(c): Failure to verify finished batch of dietary supplement meets production specification for identity, purity, strength, composition, or limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement **(33)**

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Highlights of Recent FDA Inspections: Form 483 Observations (cont'd)

- 21 CFR 111.255(a): Failure to prepare a batch production record every time a batch of dietary supplement is manufactured **(25)**
- 21 CFR 111.205(a): Failure to prepare or follow a written master manufacturing record for each unique formulation of a dietary supplement that is manufactured **(25)**
- 21 CFR 111.83(a) Failure to collect and hold reserve samples of packaged and labeled dietary supplements that have been distributed **(23)**
- 21 CFR 111.503: Failure to establish and follow written procedures for when a returned dietary supplement is received **(22)**
- 21 CFR 111.535(b)(1): Failure to make and keep records of written procedures for fulfilling requirements for returned dietary supplement **(22)**
- 21 CFR 111.65: Failure to implement quality control operation to ensure the quality of the dietary supplement **(20)**
- 21 CFR 111.75(c)(2): Failure to conduct appropriate tests or examinations to determine compliance with the specifications established for identity, purity, strength, composition, or limits on contamination that may adulterate or that may lead to adulteration od the dietary supplement **(20)**

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Highlights of Recent FDA Warning Letters

- Many FDA Warning Letters issued in 2016 about dietary supplements reflected these same cGMP violations listed in Form 483s.
- Also, misbranding, adulteration, and unapproved new drug citations.
- Violations were frequently observed during facility inspections.
  - Labeling and other printed materials are collected during these inspections and is reviewed for compliance
- FDA also reviews websites and social media pages, such as Facebook.

Highlights of Recent FDA Warning Letters (cont'd)

- Private label distributors **must** ensure that the products they release into interstate commerce comply with applicable dietary supplement regulations:
  - "As a distributor that contracts with other manufacturers to manufacture, package, and label dietary supplements that your firm releases for distribution under your firm's brand name, *FDA considers you to be ultimately responsible for the dietary supplements you introduce or deliver for introduction into interstate commerce*."
  - "Although your firm may contract out dietary supplement manufacturing operations, it cannot, by the same token, contract out its ultimate responsibility to ensure the dietary supplements it places into commerce (or causes to be placed into commerce) are not adulterated for failure to comply with dietary supplement CGMP requirements […]. In particular, the Act prohibits a person from introducing, delivering for introduction, or causing the delivery or introduction into interstate commerce of a dietary supplement that is adulterated […]. *Thus, a firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations for it is responsible for ensuring that the product is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations*."
  - "You must establish a system of production and process controls to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR 111.55). You must establish and follow written procedures for the responsibilities of the quality control operations (21 CFR 111.103). The quality control personnel must ensure that your operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR 111.105). Further, you must have documentation of the quality control personnel review and approval for release of any packaged and labeled dietary supplement [21 CFR 111.127(h) and 111.140(b)(2)]."

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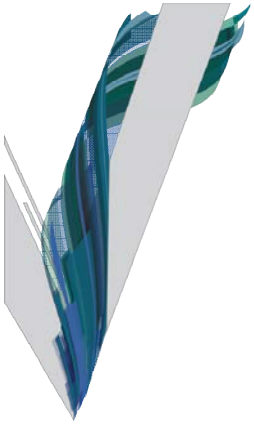
Highlights of FDA Warning Letters

- Most Warning Letters also included misbranding violations, so it's important to ensure that product labeling includes all required information, in the correct location on the label and in the correct order (as applicable).
- Misbranding violations cited include:
  - Incorrect serving size declaration
  - Failure to declare **each** ingredient in the dietary supplement, including ingredients used to make the capsules if the product is manufactured into capsules
  - Failure to identify plant part from which a botanical dietary ingredient is derived

Highlights of FDA Warning Letters

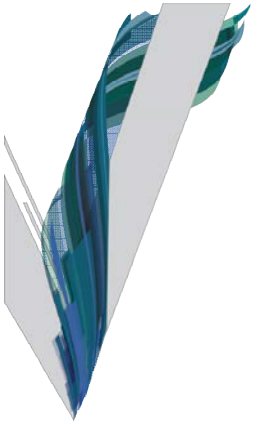
- A number of Warning Letters also included violations in the category of "unapproved new drugs."
- Most of these citations were based on FDA's review of labeling and other printed material, testimonials, and the company's website.
  - Claims found to be violative include:
    - "…[P]atent pending grape seed product from […] that reduces blood pressure by relaxing the blood vessels.
    - "Testimony No. 3: Bronchitis . . . […] after I took it. I got rid of my bronchitis in 2 days."
    - "[…] nutritional formula supports eye conditions such as Cataract, Glaucoma, Age-Related Macular Degeneration, dry eyes . . ."



Other Recent Developments at the FDA

FDA and Dietary Supplements: Hot Topics

- Public meeting (March 9) to discuss the use of "healthy" in food labeling.
- Feb. 2017:
  - FDA won a consent decree of permanent injunction against a Louisiana manufacturer and distributor of drugs and dietary supplements.
  - In California, FDA won another consent decree of permanent injunction against a distributor of a dietary supplement regarding products containing an unsafe ingredient (an amphetamine derivative).
  - Both of these actions taken after FDA inspections and Warning Letters.



FTC Enforcement Trends

Overview of FTC Authority

- The FTC has authority over advertising for all products– except prescription drugs and medical devices—under the Federal Trade Commission Act

- An "advertisement" subject to FTC jurisdiction can include marketing materials in any media—print, electronic (online), television, radio, or verbal representations of sales staff

- The FTC may challenge an advertisement based on the fact that it is:
  - False or deceptive
  - Likely to mislead reasonable consumers
  - Likely to influence consumer purchasing decisions or otherwise affect important consumer decisions

Overview of FTC Authority: Claim Substantiation Standard

- FTC requires "*competent and reliable scientific evidence*" to substantiate all health and safety claims for dietary supplements

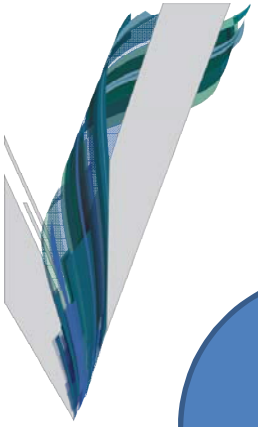
- Defined in FTC cases as:
  - Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area
  - That have been conducted and evaluated in an objective manner by persons qualified to do so,
  - Using procedures generally accepted in the profession to yield accurate and reliable results.

Overview of FTC Authority: Substantiation Standard

- In practice, the "old" standard:
  - "Competent and reliable scientific evidence" is defined in various FTC Consent Orders as "*at least **two** adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product*, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true."

Overview of FTC Authority: Substantiation Standard

- "New" Standard?
  - *Changes after Pom Wonderful LLC v. FTC (Jan. 2015)*:
    - Some RCT substantiation required for disease claim
    - But, District Court rejected FTC's rigid *two RCTs* requirement
    - Did not opine whether the standard applied to structure/function claim
  - *United States v. Bayer (Sept. 2015)*:
    - District Court stressed flexibility and importance of the opinion of experts in the field
    - Found that Bayer did not violate the requirement to possess "competent and reliable scientific evidence" merely because the company did not satisfy the exacting standard (i.e., gold standard studies) that the government's expert would have required



Takeaway # 1:

While 2 RCTs may no longer be required, clinical study data is still key to substantiating claims. Any study should be well-designed, ideally with the protocol vetted by an independent-third party and the results supported by independent scientific experts

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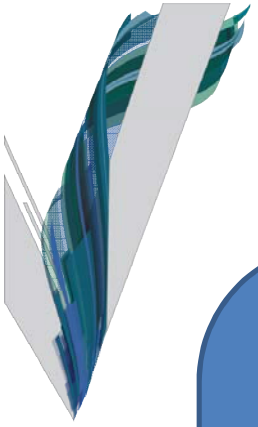
Hot-Button Claims

- Cognitive Improvement Claims
  - *Prevagen* (Jan. 2017): FTC & New York AG filed a federal court complaint for claims that a protein derived from jellyfish can improve memory and reduce memory problems associated with aging
  - *CogniPrin* (Feb. 2017): FTC & Maine AG complaint and settlement with three marketers for claims that product reverses mental decline by 12 years and improves memory

- Weight Loss Claims
  - E.g., Green Coffee Bean Extract Settlements: FTC settled several cases regarding claims that green coffee bean extract results in weight loss

Hot-Button Claims

- Immunity Claims
  - Claims to build, strengthen, increase immune system or immune response
- Natural Claims
  - Four FTC Final Consent Orders: companies allegedly misrepresented their personal care products as "All Natural" or "100% Natural" despite containing man-made ingredients
- Organic Claims
  - September 2016, FTC and USDA Roundtable on Consumer Perceptions of "Organic" Claims



Takeaway # 2:

FTC remains interested in traditional health and safety claims for dietary supplements and is also actively enforcing against other product/ingredient attribute claims

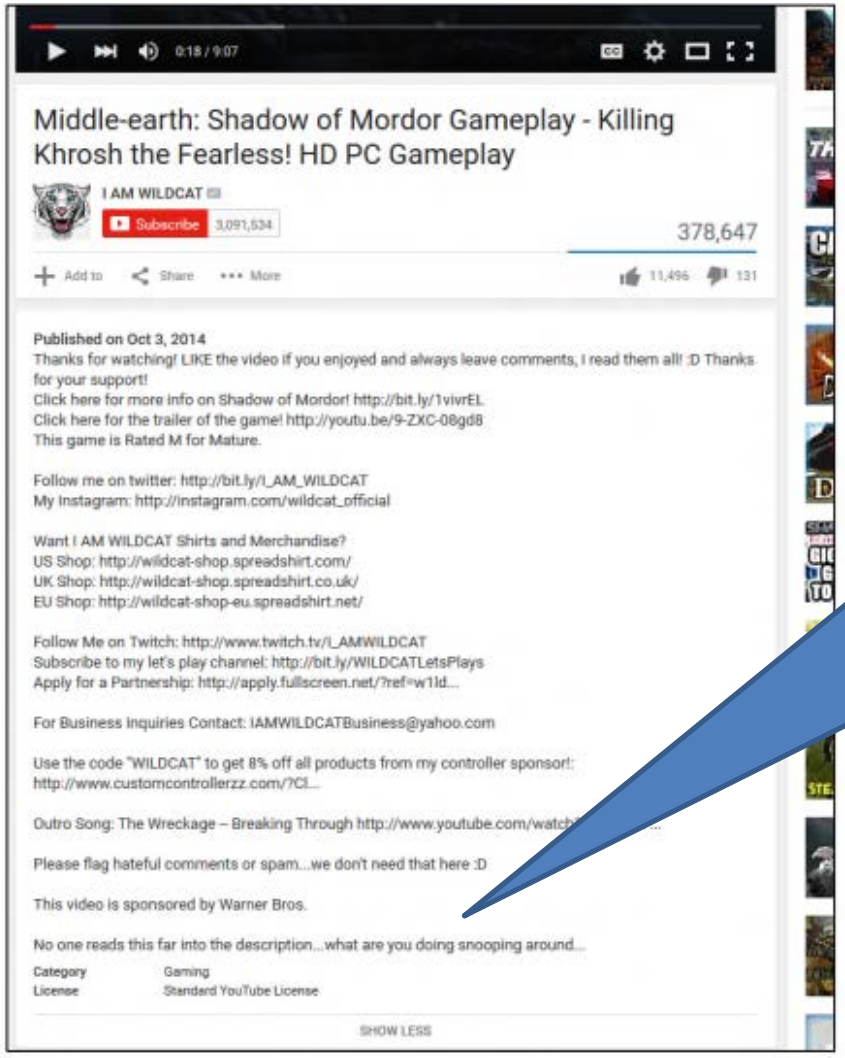
FTC Expanding its Reach: Homeopathic Products

- On November 15, 2016, FTC announced a new "*Enforcement Policy Statement on Marketing Claims for Over-the-Counter (OTC) Homeopathic Drugs*"
- Companies must have the same competent and reliable scientific evidence for efficacy and safety claims as required for other products
- FTC expanding its authority into drug market that had been exclusively regulated by FDA

New Advertising: Social Media Influencers

- Warner Bros. Settlement (July 2016)
  - Settled FTC charges that it deceived consumers during a marketing campaign for the video game *Middle Earth: Shadow of Mordor*
  - Allegedly ***failed to adequately disclose*** that it:
    - Paid online "influencers," including the popular "PewDiePie," thousands of dollars to post positive gameplay videos on YouTube and social media
    - Gave them a free advance-release version of the game
    - Told them how to promote it, according to the complaint.
  - FTC complaint alleged that Warner Bros. required the influencers to promote the game in a positive way and not to disclose any bugs or glitches they found

New Advertising: Warner Bros. Settlement



"This video is sponsored by Warner Bros

No one reads this far into the description, why are you snooping around"

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New Advertising: Testimonials Are Claims Too!

- An advertisement employing endorsements will be interpreted as representing that the product or service is effective for the purpose depicted in the advertisement
  - If the Company couldn't substantiate the claim on its own, then it should not use third party testimonials to promote the claim
- No gag clauses
- Must **clearly disclose** any material connection between the endorser and the company

New Advertising: Native Advertising and Advertorials

- Native ads often resemble the design, style, and functionality of the media in which they are disseminated
  - "Advertorial" is an advertisement that is made to look like a news editorial

- FTC requires clear disclosure that any such marketing publication is, in fact, an advertisement

Lord & Taylor Settlement (May 2016)

Retailer settled FTC charges that it deceived consumers through native ads, by paying for a seemingly objective magazine article promoting the company's fashion line and by failing to disclose the use of pay social media influencers

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New Advertising: Tips for Proper Disclosure of Native Ads

- Understandable to the Consumer:
  - "Ad," "Advertisement," "Paid Advertisement," "Sponsored Advertising Content"
  - "Promoted by" may not be sufficient

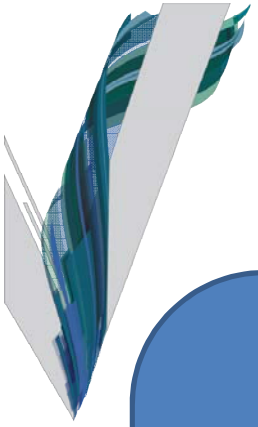
- Advertising disclosures should stand out so consumers can easily read or hear them

- Place disclosures in front of or above the headline of the native ad

New Advertising: Appropriate Disclosure

- FTC Public Workshop: Putting Disclosures to the Test
  - September 15, 2016

- Explored how to test the effectiveness of disclosures to ensure consumers notice them, understand them and can use them in their decision-making



Takeaway # 3:

Clear and conspicuous **disclosures** are key! Endorsers/influencers should not be used to say claims that you cannot

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Final Word about Marketing Practices

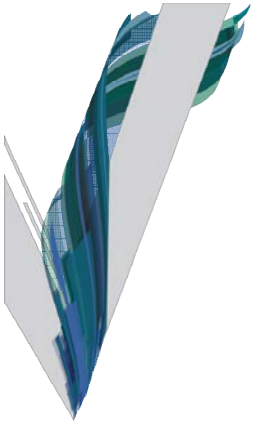
The following practices have recently been subject to FTC enforcement:

- Risk-Free Trials
  - Products pitched with risk-free trial offers that were not free of risk
  - Free means free
- Negative Option Continuity Plans
  - Customers are enrolled to receive regular shipments of a product at a set rate until they cancel

Looking Forward

- New Administration, New Chairman
  - Acting Chairman Maureen K. Ohlhausen
  - Acting Director of Bureau of Consumer Protection, Thomas Pahl

- Enforcement priorities:
  - "Bread and Butter" Fraud Cases
  - Focus on clear consumer harm
  - Focus on transparency and business education



Break

Hot Topics in Food, Beverage, and Dietary Supplement Class Action Litigation

Session Speakers:

Dan Silverman, Esq.
Partner,
Class Action Litigation,
Venable LLP

Bety Javidzad, Esq.
Counsel,
Class Action Litigation,
Venable LLP

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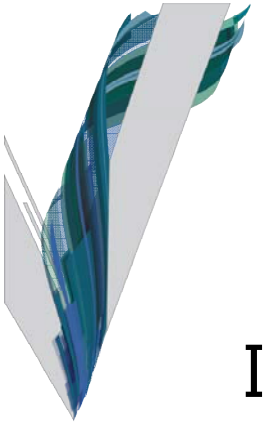
Overview

- Most common jurisdictions for false advertising class action filings?
- What are plaintiffs attacking?
- What were the significant developments in food, beverage, and supplement class action law over the past year?
- Takeaways



In 2016, more than 75% of false advertising class actions were filed in the following jurisdictions:

- California (36%)
- New York (22%)
- Florida (12%)
- Illinois (7%)

What Are Plaintiffs Attacking?

- "All natural" claims
- Evaporated cane juice claims
- "Organic" claims
- GMO claims
- Slack-fill claims
- Ingredient claims
- Healthy "inference" claims
- Lack of substantiation claims
- Ascertainability

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Regulation of "Natural" Claims

- USDA regulates labeling of meat and poultry products
  - USDA's informal position on "natural" is "not containing any artificial flavor or flavoring, coloring ingredient, or chemical preservatives" or a synthetic ingredient and not more than minimally processed
- FDA has jurisdiction over labeling of foods not regulated by the USDA
- FTC has jurisdiction over labeling and marketing of food and consumer products
  - FTC does not have an official position on "natural"

"All Natural" Claims – Delay in Regulatory Action

- **May 2016:** Comment period for FDA's evaluation of the term "natural" on food labeling ended
  - FDA has not yet issued a determination or rule on the issue
  - FDA has clearly identified that it is only evaluating the term "natural" with respect to food products

Parties Seek Stays of Food Litigation in Light of Pending FDA Guidance

- *Kane v. Chobani*, 45 F. App'x 593 (9th Cir. 2016)
  - Plaintiffs challenged "natural" and "evaporated cane juice" claims
  - 9th Cir. reversed dismissal of claims, holding the case should be stayed under primary jurisdiction until the FDA issues its determination

- Many other district courts have followed suit and stayed litigation regarding "natural" in food products
  - *Maxwell v. Unilever United States Inc.*, 2016 WL 5110498 (N.D. Cal. March 30, 2016)
  - *In re Hain Celestial Seasonings Products Consumer Litig.*, 2016 WL 6302513 (C.D. Cal. May 10, 2016)
  - *Viggiano v. Johnson & Johnson*, 2016 WL 5110500 (C.D. Cal. June 21, 2016)
  - *Anderson v. The Hain Celestial Grp.*, No. 14-cv-03895, Dkt. 62 (N.D. Cal. April 8, 2016) (stayed by stipulation)
  - *Ham v. Hain Celestial Group Inc.*, 3:14-cv-02044 (Dec. 10, 2015 N.D. Cal.)

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Pending FDA Guidance DOES NOT Stay "Natural" Claims for Non-Food Products

- *Astiana v. Hain Celestial Group, Inc.*, 783 F. 3d 753 (9th Cir. Feb. 2015)
  - Ninth Circuit reversed and remanded a dismissal of cosmetics "natural" claims on grounds of FDA's primary jurisdiction
  - "When a court invokes primary jurisdiction but further judicial proceedings are contemplated, then jurisdiction should be retained by a stay of proceedings, not relinquished by a dismissal." *Id.* at 761.

- *Astiana v. Hain Celestial Group, Inc.*, 11-cv-6342, Dkt. No. 114 (N.D. Cal. Oct. 9, 2015)
  - District Court denied request to stay the litigation on the ground of primary jurisdiction (granted the stay on other grounds) because of an FDA letter stating that it "decline[s] to make a determination regarding the term 'natural' in cosmetic labeling at this time."

Settlements of "All Natural" Claims in 2015-2016

- Monster Beverage: Settlement not yet approved
- Annie Chun's: $1.5 settlement rejected by the court
- Kashi: Up to $4 million to class members, $1.5 in attorneys' fees (preliminary approval)
- Jamba Juice: Incentive award of $5,000 to class representatives + $400K in attorneys' fees, label revisions
- Great Value Corn Starch: Up to $825,000 to class members + $5,000 to class representative (preliminary approval)
- Flaxmilk: $260,000 settlement fund + $5,000 to named plaintiff
- Ghirardelli: $5.25 million settlement fund + $5,000 to each named plaintiff
- Merisant stevia products: $1.65 million settlement fund + $4,000 to named plaintiff
- Seventh Generation: $4.5 million settlement fund
- People against Dirty and Method Products: $2.8 million settlement fund (final approval pending)

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Evaporated Cane Juice Claims

- FDA's 2009 draft guidance
  - "Evaporated cane juice" is misleading

Court's Stay of Evaporated Cane Juice Claims

- Based on FDA's draft guidance, a slew of consumer class actions challenged "evaporated cane juice" claims
- Because FDA issued only a draft guidance, and was still evaluating the issue, a majority of courts stayed "evaporated cane juice" litigation pending FDA's final guidance under primary jurisdiction
  - *Swearingen v. Late July Snacks LLC*, 3:13-cv-04324 (N.D. Cal.)
  - *Swearingen v. Santa Cruz Natural Inc.*, 3:13-cv-04385 (N.D. Cal.(
  - *Reese v. Odwalla*, 4:13-cv-00947 (N.D. Cal.)
  - *Figy v. Lifeway Foods,* 3:13-cv-04828 (N.D. Cal.)

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FDA's Final Guidance on Evaporated Cane Juice

- May 2016 – FDA's Final Guidance
  - "Evaporated cane juice" is misleading
  - FDA recommends using "sugar" instead
    - FDA Guidance is relevant, but not binding; it is evidence of whether a "reasonable consumer" would find "evaporated cane juice" misleading

Courts Are Lifting Stays re: Evaporated Cane Juice

- Courts are lifting the stayed cases following FDA's final guidance
  - *Swearingen v. Late July Snacks LLC*, 3:13-cv-04324 (N.D. Cal.)
  - *Swearingen v. Santa Cruz Natural Inc.*, 3:13-cv-04385 (N.D. Cal.)
  - *Reese v. Odwalla*, 4:13-cv-00947 (N.D. Cal.)
  - *Figy v. Lifeway Foods,* 3:13-cv-04828 (N.D. Cal.)
- Many new cases have been filed seeking to take advantage of FDA's determination that "evaporated cane juice" is misleading

What Are Plaintiffs Attacking? "Organic" Claims

- USDA regulations preclude the use of genetically modified organisms in the production of "organic" products (7 C.F.R. § 205.2)
  - The following methods are considered genetic modification:
    - Cell fusion
    - Microencapsulation and macroencapsulation
    - Recombinant DNA technology

What are Plaintiffs Attacking? "Organic" Claims

- Organic Claims – Split Over Preemption
  - *Segedie v. The Hain Celestial Group, Inc.*, Case No. 14-cv-5029 (S.D.N.Y. May 7, 2015)
    - Case involved food and personal care products certified as "organic" alleged as misleadingly labeled in violation of state consumer protection laws
    - *Denied* motion to dismiss on preemption grounds, despite federal regulation that certified the products as "organic"
      - *Rejected* 8th Circuit precedent that claims directly challenging federal certification were, in fact, preempted
  - *Marentette v. Abbott Labs.,* Case No. 15-cv-2837 (E.D.N.Y. Aug. 23, 2016)
    - Case involved baby formula certified as organic but allegedly containing impermissible ingredients under USDA regulations
    - *Granted* motion to dismiss as preempted because organic claim had been certified by an accredited certifying agency under federal regulation

What Are Plaintiffs Attacking? "Organic" Claims

- *Quesada v. Herb Thyme Farms Inc.* (Dec. 3, 2015 Cal. Sup. Ct.)
  - Defendant mixed organic and non-organic herbs in the same package
  - The court found that state consumer protection claims were not preempted by the federal Organic Foods Act

Rise of GMO Claims

- Two types of food labeling issues re: GMO claims:
  - Voluntary claims that a product does not contain GMOs
  - Consumer activists and state/federal agencies seeking to impose mandatory labeling requirements

State Regulation of GMO Claims

- Vermont Labeling Law (Vermont Act 120, 9 V.A.S. § 3041, *et seq.*):
  - Mandatory GMO labeling for food products that are genetically modified or contain genetically modified ingredients
  - "Genetically engineered" means a food from one organism in which the genetic material has been changed
- Two states passed labeling requirements that have not yet gone into effect:
  - Connecticut
  - Maine

FDA's Regulation of GMO Claims

- FDA issued guidance in Nov. 2015 on how food makers can label genetically engineered food products, but still does not require it
  - "Genetic engineering" refers to the use of modern biotechnology on food or its ingredients
  - FDA also recommends against the use of "non-GMO" and "GMO free" because the reference to "organism" is not precise

USDA GMO Regulations

- USDA regulations preclude the use of genetically modified organisms in the production of "organic" products (7 C.F.R. § 205.2)
  - The following methods are considered genetic modification:
    - Cell fusion
    - Microencapsulation and macroencapsulation
    - Recombinant DNA technology

Recent Federal Express Preemption

- Pub. Law 114-216: GMO Labeling Act
  - Signed into law by Pres. Obama on July 29, 2016
  - Requires certain labeling of genetically modified foods
  - Preserves authority of FDA to regulate labeling of GMO foods
    - Secretary has until 2018 to finalize regulations
  - State and local labeling requirements are expressly preempted

GMO Labeling: Voluntary Compliance

- SmartLabel
  - Advocated by GMA
  - Information accessed by scanning QR code on product with smartphone, searching online or through an app
  - Allows consumers to access more information about a product's ingredients online

- Campbell Soup Company
  - January 2016
    - Announces voluntary GMO labeling
    - Announces support for nationwide mandatory GMO labeling

GMO-related Litigation: Motions to Dismiss

Defendant success

- *Gallagher v. Chipotle Mexican Grill, Inc.*, 3:15-cv-03952 (Feb. 5, 2016 N.D. Cal.)
  - Dismissed with leave to amend
  - Plaintiff failed to specify which of defendant's "Food Products" she purchased and, therefore, whether they contained GMOs
  - No standing for injunctive relief since plaintiff does not intend to purchase defendant's products in the future
  - Court noted that plaintiff's definition of "GMO" was inconsistent with her interpretation of defendant's GMO claims: animal products are not themselves GMO, only consumed GMO feed
- *Reilly v. Chipotle Mexican Grill, Inc.*, 1:15-cv-23425 (S.D. Fla.)
  - Granted Chipotle's Motion for Summary Judgment
  - Plaintiff failed to establish that a reasonable consumer would believe that meat and diary ingredients sourced from animals that have consumed GMO feed are, or contain, GMOs
  - Plaintiff failed to establish any harm because she paid the same amount for food purchased at Chipotle prior to the announcement that the ingredients are free of GMOs

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GMO-related Litigation: Motions to Dismiss

Plaintiff success (case settled in Feb. 2016)

- *Eggnatz, et al. v. The Kellogg Company, et al.*, 1:12-cv-21678 (Sept. 5, 2014 S.D. Fl.)
  - On a motion to dismiss, defendants argued that plaintiff's claim re "natural"-ness of GMO-containing Kashi products was preempted
    - The Court disagreed, finding that there was no express preemption in any statute, and the claims were not impliedly preempted because the FDA has not regulated the term "all natural," nor does it have a policy permitting foods containing GMOs to be described as natural

GMO-related Litigation: Class Certification

Defendant success

- *Ault v. J.M. Smucker Co. et al.*, 1:13-cv-03409 (Aug. 6, 2015 S.D.N.Y.)
  - Class certification denied over claims that GMO-based Crisco products were mislabeled as "all natural"
    - Plaintiff did not establish ascertainability
      - Defendants do not have records of individual sales
      - Most consumers who purchased the product do not have records
      - Labels varied among the challenged products: Only four of the products had the "All Natural" labelling, and by the time of the lawsuit, "natural" was phased out on all but one kind of oil

GMO-related Litigation: Class Certification

Plaintiff success

- *Briseno v. Conagra Foods, Inc.*, 2:11-cv-05379 (Feb. 23, 2015 C.D. Cal.)
  - Court certified 11 statewide classes of consumers of "all natural" Wesson oil products, denying only certification of injunctive relief class
    - Every bottle carried the same label, unlike in *Ault v. J.M. Smucker Co.*

What Are Plaintiffs Attacking? Slack-Fill Claims

- 21 C.F.R. § 100.100(a)
  - Slack fill is the empty space in a container or packaging
  - A product's packaging may be misleading "if it contains non-functional slack-fill"
  - "Non-functional slack-fill" is empty space that serves no purpose in an opaque package
- Cal. Bus. & Prof. Code § 12606.2
  - Incorporates federal regulations
  - No food containers shall be made, formed, or filled so as to be misleading
  - Misleading if it contains "nonfunctional slack fill"
  - "Nonfunctional slack fill is the empty space in a package that is filled to substantially less than its capacity other than for [certain enumerated reasons]."
  - Exceptions to nonfunctional slack fill include:
    - Protection of the contents of the package
    - Requirements of the machine used to enclose the contents
    - Settling during shipping and handling
    - Need for packaging to perform a specific function
    - Food packaged in a reusable container with empty space as part of the presentation
    - Inability to increase the fill level because the size is necessary to accommodate labeling requirements

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What Are Plaintiffs Attacking? Slack-Fill Claims

- *Hendricks v. Starkist Co.*, 3:13-cv-00729 (May 2015 N.D. Cal.)
  - Starkist settled slack-fill claims on its tuna products for $12 million

- *Soto v. Safeway Inc.*, 3:15-cv-05078 (filed Nov. 15, 2015 N.D. Cal.) and *Magier v. Trader Joe's Co.*, 1:16-cv-00043 (filed Jan. 5, 2016 S.D.N.Y.)
  - Safeway and Trader Joe's fighting similar claims against same plaintiffs' counsel

What Are Plaintiffs Attacking? Slack-Fill Claims

- *In Re: McCormick & Co. Inc. Pepper Products Marketing and Sales Practices Litigation*, MDL number 2665 (D. D.C.)
  - McCormick pepper skimping claims consolidated in District of DC

- *Johana Garcia et al. v. The Procter & Gamble Co. et al.*, 1:15-cv-09174 (S.D.N.Y.)
  - Plaintiff alleges Tide products are packaged so as to mislead customers about how much actual product they're getting

What Are Plaintiffs Attacking? Slack-Fill Claims

- *Bush v. Mondelez Int'l, Inc.*, Case No. 16-2460, 2016 WL 5886886 (N.D. Cal. Oct. 7, 2016)
  - Suit focused on slack fill in cookie products
  - *Granted* motion to dismiss. Reasonable consumer could not be misled by empty space in cookie pouches because labeling revealed net weight and number of cookies or crackers
  - No other false labeling to contradict truthful net weight labels

- *Izquierdo v. Mondelez Int'l*, Case No. 16-cv-4697 (S.D.N.Y. Oct. 26, 2016)
  - Suit focused on slack fill in Sour Patch Kids candy products
  - *Granted* motion to dismiss because plaintiff failed to establish that he paid a premium for the candy. Plaintiff relied on "deception as injury" theory that has been rejected by 2nd Cir. and fails to attempt to allege how a "premium" was charged.

- *Fermin v. Pfizer, Inc.*, 2016 U.S. Dist. LEXIS 144851 (E.D.N.Y. Oct. 18, 2016)
  - Suit focused on slack fill in ibuprofen
  - *Granted* motion to dismiss. Reasonable consumer could not be misled regarding the number of pills in the bottle based on the size of the bottle when the label clearly and unambiguously identifies the total number of pills contained in each package.

What Are Plaintiffs Attacking? Slack-Fill Claims

- *Bautista v. CytoSport, Inc.*, Case No. 7:2015-cv-9081 (S.D.N.Y. Dec. 12, 2016)
  - Plaintiff alleges that the roughly 30% of empty space in Defendants' Muscle Milk product was unlawful slack fill.
  - *Granted* motion to dismiss SAC with prejudice. To survive a motion to dismiss, a plaintiff must provide facts that the empty space in the product packaging was not used "to protect product, necessary for enclosing the product, or because of settling." Conclusory allegations are insufficient to state a nonfunctional slack-fill claim.

- *Ebner v. Fresh, Inc.*, 838 F.3d 958 (9th Cir. 2016)
  - *Affirmed grant* of motion to dismiss claims
  - No reasonable consumer would be misled that 25% of the lip balm was not accessible due to the plastic stop device
    - The portion of the lip balm falling below the stop device does not constitute slack fill, which is only the empty space in the product packaging
    - Furthermore, the product packaging was not misleading, because it accurately identified the amount of product, even if plaintiff is correct that not all was accessible
    - Last, the packaging itself was not misleading because no reasonable consumer expects the weight and size of packaging to reflect directly the quantity of product contained therein

- In October, 2016, one attorney (Scott Kamber) filed 11 slack-ill lawsuits in Missouri against candy and fruit snack companies

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What Are Plaintiffs Attacking? Ingredient Claims

- Name of product or packaging names ingredient(s) only present in small amounts in the product or the ingredient does not provide the benefit advertised
- Recent examples to watch:
  - *Segovia v. Vitamin Shoppe, Inc.*, 7:14-CV-7061 (S.D.N.Y.)
    - Plaintiff claims that Defendants' product falsely claimed that the 100% Casein is "enhanced with Aminogen, an enzyme that helps your body break down and absorb protein." Plaintiff alleged that Defendant's dosage of 25mg of aminogen is a fraction of the clinical dosage identified to achieve the advertised benefit.
  - *Gyorke-Takatri, et al., v. Nestle USA Inc. et al.*, CGC-15-546850, (Cal. Sup. Ct., San Francisco)
    - Plaintiffs claim Gerber Puffs cereal depicts fruits and vegetables on box but contains hardly any of those ingredients

What Are Plaintiffs Attacking? Ingredient Claims

- *Sonner v. Schwabe North America, Inc., et al.,* EDCV 15-1358 (C.D. Cal.)
  - District Court granted summary judgment in favor of defendant
    - Plaintiff alleged that Defendant's ginkgo biloba product cannot scientifically achieve the advertised mental health benefits
    - Both parties submitted scientific expert reports establishing their respective positions of the state of the scientific literature regarding the benefits of ginkgo biloba
    - District court granted summary judgment, despite the battle of the experts, because a dispute among experts is insufficient to sustain plaintiffs' burden that the representations are false

- *Porter v. NBTY, Inc., et al.*, 1:15-cv-11459 (N.D. Ill.)
  - District Court denied Defendants' motion to dismiss the substantive fraud claims for protein spiking
    - Plaintiffs claim that Defendants improperly added nitrogen-containing, cheap, and less beneficial free-form amino acids and non-protein ingredients in their products to create a misleading protein measurement in the product

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What Are Plaintiffs Attacking? Healthy Inference Claims

- FDA regulations govern "healthy" as an implied nutrient content claim
  - Used to suggest that a food may help maintain healthy dietary practices and
  - Made in connection with an explicit claim (e.g., "healthy, contains 3g of fat")

- Regulation requires that foods be low in fat, saturated fat, cholesterol, and sodium, and that they contain at least 10% of one or more qualifying nutrients

What Are Plaintiffs Attacking? Healthy Inference Claims

- FDA 2016 Guidance Document on "healthy" claims
  - Enforcement discretion toward products with disqualifying amounts of total fat, if the majority of total fat is unsaturated
  - Enforcement discretion toward products with at least 10% of the DV of non-qualifying nutrients vitamin D or potassium

- It is unclear whether FDA will redefine "unhealthy"

What Are Plaintiffs Attacking? Healthy Inference Claims

- *Stoltz et al. v. Fage Dairy Processing SA et al.*, 1:14-cv-03826 (Sept. 22, 2015 E.D.N.Y.)
  - Plaintiffs claim they were misled by "0%" label, without any context as to what "0%" means, leaving plaintiffs to impute any meaning to the 0% that consumers wish
  - Court denied defendants' motion to dismiss consumer protection claims
    - Nutrition Facts panel, as a matter of law, does not foreclose the possibility that a reasonable consumer might be misled by the product
    - Court did not agree that consumers would assume that "0%" referred to "non-fat," which was also present on the label

What Are Plaintiffs Attacking? Healthy Inference Claims

- *Atik v. Welch Foods, Inc. et al.*, 15-cv-5405 (E.D.N.Y.)
  - Plaintiffs claim that Defendants' fruit snacks products' representation that it is made with real fruit and fruit is the first ingredient is false and misleading because it implies that the product is healthy
    - Court denied defendants' motion to dismiss consumer protection claims

What Are Plaintiffs Attacking? Healthy Inference Claims

- Plaintiffs' lawyers have sued over products containing even small amounts of trans fat following the FDA's June 2015 decision that partially hydrogenated oils are no longer Generally Recognized as Safe (GRAS)
  - But FDA regulations continue to *require* products containing less than 0.5g trans fat per serving to be labeled "0g trans fat"

What Are Plaintiffs Attacking? Healthy Inference Claims

- Previously, courts often dismissed "0g trans fat" claims on the pleadings as preempted
  - *Troy Backus et al. v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068 (N.D. Cal. Mar. 9, 2016) (appeal pending)
    - "0g trans fat" claim preempted
  - *Troy Backus et al. v. ConAgra Foods, Inc.*, Case No. 16-cv-454, 2016 WL 3844331 (N.D. Cal. Jul. 15, 2016)
    - Court dismissed "0g trans fat" and "no trans fat" claims as preempted, but allowed "healthy lifestyle" claim to move forward
  - Under *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. Mar. 13, 2015), "no trans fat" claims are not preempted or subject to primary jurisdiction doctrine
    - The court found that "no trans fat" label is different from "0g trans fat" because the former is a nutrient content claim, while the latter is a required statement under FDA regulations

What Are Plaintiffs Attacking? Health Benefit Claims

Recent Examples

- *Veda Woodard v. Lee Labrada et al.*, 2:16-cv-00717 (filed Feb. 2, 2016 C.D. Cal.)
  - Dr. Oz sued for promoting "fat-busting" nutritional supplements

- *Worth et al. v. CVS Pharmacy Inc.*, 2:16-cv-00498 (Feb. 1, 2016 E.D.N.Y.)
  - Plaintiffs challenging "clinically shown" claims on supplement labels

What Are Plaintiffs Attacking? Health Benefit Claims

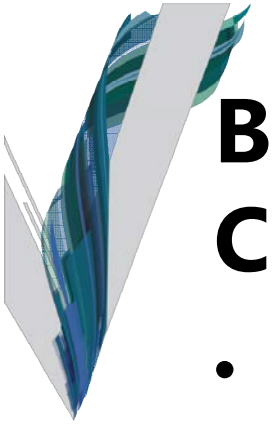
Defendant wins

- *Kaufman et al. v. CVS Caremark Corp. et al.*, 1:14-cv-00216 (Jan. 28, 2016 D. R.I.)
  - Complaint alleging fraudulent labelling of Vitamin E supplements as "heart healthy" dismissed
    - Statements on the label were in compliance with FDCA requirements, and at least somewhat supported by scientific studies
    - Disclaimer that supplement "is not intended to diagnose, treat, cure or prevent any disease" complies with FDCA requirements

What Are Plaintiffs Attacking? Health Benefit Claims

Plaintiff wins

- *Sarah A. Salazar et al. v. Honest Tea Inc.,* 2:13-cv-02318 (Nov. 12, 2015 E.D. Cal.)
  - Plaintiff claimed that antioxidant labels on Honest Tea are misleading
  - Defendants moved for summary judgment on basis of Plaintiff's testimony that she did not purchase the product with the challenged label, admitted that the statements on the label are true, and was not familiar with FDA regulations when she purchased the product
  - Court denied the motion
    - Even though Plaintiff bought different product, there was sufficient similarity between the products
    - A statement need not be untrue to be misleading
    - Plaintiff need not know about FDA regulations if statement on label created expectations in consumers' mind that were not met



Bar on Private Lack of Substantiation Claims

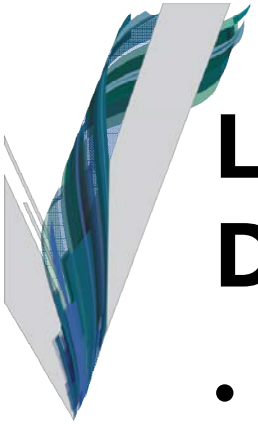
- Private plaintiffs may not bring claims on the basis of a lack of substantiation (i.e., that defendants' advertising claims lack adequate scientific substantiation); instead, private plaintiffs bear the burden of proving the challenged advertising claims are false or misleading.
  - *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th (Cal. Ct. App., 2nd Dist. 2003)

Lack of Substantiation Bar: Recent Decisions

- In light of the bar on lack-of-substantiation claims, private plaintiff making false advertising claims must point to scientific evidence that disproves the defendants' advertising claims
  - *Engel v. Novex Biotech LLC*, 2015 WL 846777 (N.D. Cal. Feb. 25, 2015)
  - *Route v. Mead Johnson Nutrition Co.*, 2013 WL 658251 (C.D. Cal. Feb. 21, 2013)

Lack of Substantiation Bar: Recent Decisions

- *In re GNC Corp.,* 789 F.3d 505 (4th Cir. 2015)
  - Affirmed dismissal of claims brought under the consumer protection statutes of various states
  - Found that plaintiffs had failed to plead that the representations on defendant's product packaging were false because "[w]hen litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is 'literally false'"
  - Held that, in order to state claim for actual falsity under consumer protection statutes, a plaintiff must allege that all reasonable experts in the field agree that the representations are false



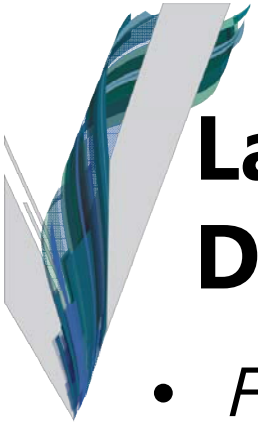
Lack of Substantiation Bar: Recent Decisions

- *Aloudi v. Intramedic Research Grp., LLC*, 2015 WL 4148381 (N.D. Cal. July 9, 2015)
  - Holding that evidence disproving an advertising claim must actually be tied to the specific representations made in the advertising
  - Dismissing false advertising claim because plaintiff's evidence (which purportedly disproved defendant's advertising claims) related to caffeine and coffee generally, and not to defendant's coffee bean extract weight loss product specifically

Lack of Substantiation Bar: Recent Decisions

- *Kwan v. SanMedica Int'l, LLC*, 2015 WL 848868 (N.D. Cal. Feb. 25, 2015)
  - Holding that a plaintiff's evidence must show that a product's advertised benefits are "categorically impossible" to achieve

- *Engel v. Novex Biotech LLC*, 2015 WL 846777 (N.D. Cal. Feb. 25, 2015)
  - Holding that a private plaintiff cannot avoid the bar on lack-of-substantiation claims merely by pointing to "magic words" (e.g., "clinically tested") contained in a defendant's advertising claims



Lack of Substantiation Bar: Recent Decisions

- *FTC v. Prevagen, Inc. et al.*, 1:17-cv-124 (S.D.N.Y.)
  - FTC and New York Attorney General filed a complaint alleging that Prevagen's product claims (containing the primary active ingredient apoaequorin) of improved memory and other cognitive benefits are false and unsubstantiated
    - While the complaint admits that Prevagen relies upon a double-blind placebo-controlled clinical study, FTC claims that Prevagen conducted more then 30 post hoc analyses of the results to claim more positive benefits than actually reported in the study
    - FTC also alleges that Prevagen's advertising of the study's results omits the portions where the study did not find statistically significant benefits

Lack of Substantiation Bar: Recent Decisions

- *Bitton et al v. Gencor Nutrientes, Inc. et al.*, 654 Fed. Appx. 358 (9th Cir. 2016)
  - Ninth Circuit reversed the District Court's grant of Defendants' motion to dismiss
    - Plaintiffs' allegations that Defendants' representation that Testofen increases free testosterone levels is not a lack of substantiation claim, but a false advertising claim
    - Plaintiffs' attachment of scientific literature supporting their claims of false advertising is sufficient to survive at the pleading stage

Major Class Action Developments Regarding Ascertainability

- Courts have applied an additional requirement for class actions to proceed: "Ascertainability"
  - Members of the class must be sufficiently definite that they can be easily as curtained or determined using objective criteria

- Jurisdiction split
  - Third and Eleventh Circuits applied a "heightened" ascertainability requirement
  - Sixth, Seventh, and Eighth Circuits adopted a weaker requirement
  - Ninth Circuit recently rejected the Third and Eleventh Circuits' "heightened" standard

Major Class Action Developments Regarding Ascertainability – Administrative Feasibility Requirement

- *Carrera v. Bayer Corp.*, 727 F.3d 300 (3d Cir. 2013)
  - Ascertainability is required for class certification subject to "rigorous analysis" under Fed. R. Civ. P. 23
  - Analysis must be performed at the class certification stage
  - Ascertainability cannot be satisfied by class member affidavits swearing to have purchased the product
  - "[A] plaintiff must show, by a preponderance of the evidence, that the class is currently and readily ascertainable based on objective criteria [using] a rigorous analysis." *Id.* at 306.

- *Karhu v. Vital Pharmaceuticals, Inc.*, No. 14-11648 (11th Cir. 2015)
  - Aligns with *Carrera* analysis
  - District court refused to certify class of weight-loss supplement purchases because plaintiffs failed to show any objective, administratively feasible method of identifying class members
  - Eleventh Circuit affirmed
    - Use of defendants' and third-party sellers' records is not sufficient
    - Self-identification is also not sufficient

Major Class Action Developments Regarding Ascertainability – No Administrative Feasibility Requirement

- *Mullins v. Direct Digital, LLC*, 795 F.3d 654 (7th Cir. 2015)
  - Seventh Circuit ascertainability analysis is in direct conflict with *Carrera*
  - Class simply must be "defined clearly and based on objective criteria"
  - No requirement of "administrative feasibility"
- *Sandusky Wellness Ctr. V. Medtox Sci., Inc.*, 821 F.3d 992 (8th Cir. 2016)
- *Rikos v. Procter & Gamble Co.*, 799 F.3d 497 (6th Cir. 2015)
  - Both Circuits also rejected *Carrera*

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Major Class Action Developments Regarding Ascertainability – 9th Cir. Rejects Administrative Feasibility Requirement

- *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121(9th Cir. Jan. 3, 2017)
  - Ninth Circuit rejected *Carrera* – there is no "administrative feasibility" requirement under Rule 23
    - A separate administrative feasibility requirement would undermine one of the core purposes of class actions – to allow aggregate claims for what would otherwise be low-dollar claims that would not be economical to pursue
  - 9th Cir. also rejected the due process concerns raised in *Carrera*, because defendants can still contest absent class members' claims for damages when filed
  - However, ConAgra has requested that the 9th Circuit stay its mandate so it can file a petition to the U.S. Supreme Court

Takeaway Points

- Plaintiffs continue to pursue food, beverage, and supplement targets
  - Often a cluster of cases making similar claims against similar products will be brought by the same plaintiff/law firm
  - If your competitor is sued, odds are you will be too
  - Plaintiffs' attorneys trends tend to follow consumer complaint trends, so stay abreast of what consumers are concerned with

Takeaway Points

- Defendants should defend strategically
  - Know and comply with applicable regulations – they may provide effective "safe harbors" and give rise to preemption defense
  - Become familiar with cases involving similar products
    - Figure out what worked/didn't work for others
    - Identify key differences in your case and exploit them
  - While parties understandably tend to focus on the substantive merits of allegations, do not forget to carefully scrutinize damages early in the case
    - Failure by the plaintiff to sufficiently compile a damages model can lead to effective dismissal of the case

Takeaway Points

- Work with outside counsel to:
  - Review and approve advertising claims and even product packaging ***before*** they are made available to consumers
    - Use language that would make sense to a reasonable consumer
  - Consider incorporating mandatory arbitration clauses with class action waivers in all consumer contracts
  - Pay attention to consumer complaints and correspondence
    - Addressing and fixing customer complaint issues early may preempt a potential class action

Protecting Your Brand and Company Reputation: Best Practices in Fighting Food or Ingredient Fraud

Session Speakers:

Justin Pierce, Esq.
Partner and Chair,
Intellectual Property,
Venable LLP

Calvin Nelson, Esq.
Counsel,
Intellectual Property,
Venable LLP

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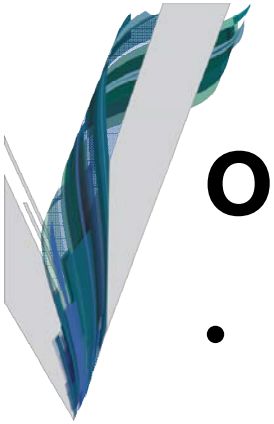

On the Hunt for Fraud in Supplements

- "When a scientific study tests numerous herbal supplements manufactured by more than a dozen companies and finds the wrong plant in just about every one, it raises more troubling questions about whether people who buy dietary supplements are getting what they pay for."
- "This is yet another sign that weaknesses in the supplements industry's approach to quality control are having real-world consequences for consumers."
  - New York Attorney General Eric Schneiderman, Press Release, September 10, 2015

"What we eat and where it comes from, generally, we don't know anymore. It's a very complex web. *Every time you have a transaction [in the supply chain], there's another opportunity to cheat.*"

– Professor Chris Elliott, Founder,
Institute for Global Food Security

Source: Natalie Whittle, "The fight against food fraud," *Financial Times*, March 24, 2016.

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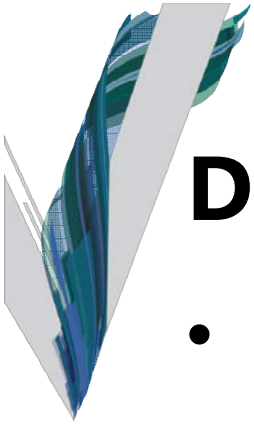


Dangers of Food and Ingredient Fraud

- Harm to consumers
- Loss of goodwill
- Consumer confusion
- Price erosion/suppression
- Brand dilution
- Lost profits
- Lost market share
- Lost opportunities

Common Food and Ingredient Fraud Scenarios

- **Contract manufacturer** supplies you with substandard materials or ingredients, you will have risk and exposure
- **Unscrupulous competitor** sells impure, substandard, or mislabeled products that compete with yours, and may look like or infringe your brand or products in some way

Proactive Strategies

- Register IP rights
- Combine and layer IP rights where possible
  - *Trademarks* cover ingredient/product name, logo, slogan, colors, packaging
  - *Patents* cover methods of extraction and specific ratio of compounds
  - *Copyrights* cover creative content, artwork, software
  - *Trade secrets* cover certain confidential and proprietary information, methods, recipes

Other Best Practices

- Increase engagement and collaboration
  - Find a way to collaborate with industry, government, academia, and nongovernmental organizations
  - Engage government as a facilitator
    - Help establish standards and share information regarding emerging threats

Response Strategies – Factors to Consider

- Budget
- The nature of the relief desired
  - Money, injunction, or both
- Which laws were violated
- The scope of the relief sought
  - Limited, national, or international
- Time frame

Contracts and Purchase Orders

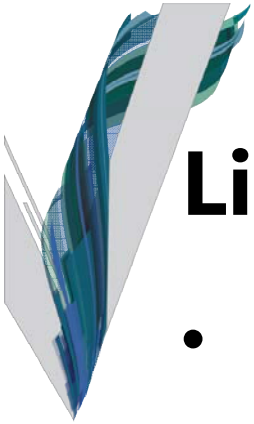
- The starting point for supply-chain management
- Good fences make good neighbors
- Clear, mutually agreed-upon, enforceable terms
  - No "gotcha" clauses
- Indemnification
  - "Trust but verify"
- Audit and quality control provisions

Cease-and-Desist Letters

- Key first step to enforcement and negotiation
- Can be used to bring a supplier into line
- When dealing with third parties, important to put infringer on notice

Litigation – The Last Resort

- Most likely in federal court
  - Amount in controversy over $75,000
  - Diversity of parties
    - Businesses in different states or countries
- Federal question
  - IP claims involving patents, trademarks, and copyrights have federal subject matter jurisdiction



Litigation Options – Pace Matters

- Temporary Restraining Order
  - Immediate (within days) hearing
  - *Ex parte* (one-sided) proceedings allowed
  - Factors required:
    - Likelihood of success
    - Irreparable harm
    - Potential harm to society
    - Balance of fairness
  - Relief limited to injunctions, 10 days

- Preliminary Injunction
  - Same factors
  - Relief stays in place until decision on merits

Litigation – The Long Haul

- Different average speeds in different courts
- From months to years
  - Motions to dismiss
  - Written discovery
  - Depositions
  - Summary Judgment
  - Pretrial
  - Trial
  - Post-trial
  - Appeals

Recent Litigation

- 2014: *Nestlé Purina PetCare Co. v. Blue Buffalo Ltd.*
  - Alleged that Blue Buffalo included poultry by-products in its pet food, despite advertising to the contrary
  - Blue Buffalo blamed its various suppliers and accused them of conspiring over a course of years to perpetuate ingredient fraud

- 2016: *Kraft Foods Grp., Inc. v. SunOpta Ingredients, Inc.*
  - Kraft learned that the dried buttermilk product it was purchasing was not pure buttermilk powder but a blend of buttermilk powder and other ingredients
  - Brought action against supplier for breach of contract, common-law fraud, and violation of the Illinois Consumer Fraud Act (ICFA)

Section 337 – A Unique Tool

- International Trade Commission (ITC)
- Has authority to block importation of products that unfairly compete with U.S. businesses
- Jurisdiction is over products, not persons

When to Consider the ITC

- Does the unfair act concern an importation, or sale for or after importation?
- Will an exclusion order and/or cease-and-desist order provide adequate relief?
- Is time of the essence?
- Infeasible or impossible to design around within 18 months?
- Widespread infringement by indeterminate sources?
- Is personal jurisdiction over the target company shaky?

ITC – Remedies

- Exclusion orders and that block imports at the border
  - Limited (LEO): Bars the named party (and its agents) from importing any articles that violate Section 337
  - General (GEO): Bars anyone from importing the articles at issue
    - Granted only where it can be shown that a LEO is likely to be circumvented
- Cease-and-desist orders that prevent sales of domestic inventories
  - Penalties for violation up to $100,000 per day or twice the value of the goods, whichever is greater
- No money damages

ITC – Proving a Violation

- Importation, sale for importation, or sale after importation of the accused products
- Unfair competition or other unfair acts associated with the imported products
- A "domestic industry" comprising certain qualifying domestic investments
- Injury or threat of injury to the domestic industry caused by the imported products
  - Can be presumed based on ownership and use of relevant patents, trademarks, copyrights, etc.

ITC – Advantages

- Investigations move fast – final decisions usually issued in 15 months or less
- Jurisdiction – *in rem* jurisdiction makes it possible to initiate an action based on a single illicit product
- Service – ITC handles serves via overnight mail; Hague Convention does not apply
- Joinder – All defendants are joined; more than 20 defendants is not uncommon

ITC – Enforcement of Exclusion Orders

- U.S. Customs and Border Protection (CBP)
  - Formally known as Customs Service
  - Within the U.S. Department of Homeland Security
- Office of International Trade
  - Regulations and Rulings; IPR Branch
- Educate Customs
  - Provide samples of infringing goods
  - Provide patent excerpts, technology tutorial
- Provide industry intelligence to Customs
  - Preferred ports, likely means of importation

ITC vs. District Court

	ITC	DISTRICT COURT
Duration	16 months or less	3 years on average
Jurisdiction	*in rem*	*in personam*
Discovery	Relatively broad	Federal Rules limit scope
Judges	6 ALJs each adjudicate 9+ patent cases/year	677 judges in 94 courts = ~1 patent case per court/year
Confidentiality	Stringent administrative protective order	Negotiated protective orders
Evidence	Relatively broad—hearsay acceptable	Fed. R. Evid.
Remedy	Exclusion orders, cease-and-desist orders	Monetary damages mostly, unless equitable *eBay* factors support injunction

VENABLE

Government Enforcement

- Sometimes it is easier to let federal or state governments do the enforcing
- Focused on preventing harm to consumers
- Pros
  - Cheap to free
  - Stronger penalties available
- Cons
  - Loss of control
  - No guarantee of action

Federal Trade Commission (FTC)

- "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45.
- FTC largely defines what is "unfair competition"
- FTC has exclusive jurisdiction to enforce

U.S. Department of Justice

- From time to time, the U.S. Department of Justice brings actions to enforce the food and drug laws on behalf of the FDA

- In 2015, U.S. Department of Justice obtained a consent decree against Health One Pharmaceuticals Inc., a California supplement manufacturer also allegedly engaged in the dissemination of unapproved new drugs

State Attorneys General

- Most states have local "Little FTC Acts" that empower state attorneys general to penalize unfair business practices

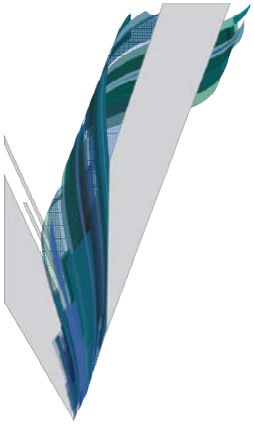
- California, New York, and Illinois are among the most active and respected

Recent State AG Actions

- New York Attorney General Eric Schneiderman's campaign against dietary supplements
  - Settlements have included commitments to use DNA barcode testing for all herbal ingredients and heightened testing standards for contamination

Self-Regulatory Bodies

- U.S. Pharmacopeial Convention (USP)
  - Promulgates standards that are well regarded by FDA and other regulators
- CRN USA
  - Suites of voluntary best practices
  - The Supplement OWL (dietary supplement product registry)
- National Advertising Division (NAD)
  - Permanent monitoring program for supplements



Questions?