

VENABLE

BAA Monthly Update

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Federal Developments: FTC

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Social Influencers

- **In the Matter of Warner Bros. Home Entertainment Inc.**

- Settled charges that Warner Bros deceived consumers during a marketing campaign for the video game *Middle Earth: Shadow of Mordor*, by failing to adequately disclose that it paid online “influencers” thousands of dollars to post positive gameplay videos on YouTube and social media.
- FTC alleged that Warner Bros. paid each influencer from hundreds to tens of thousands of dollars, gave them a free advance-release version of the game, and told them how to promote it. The FTC contended that Warner Bros. did not tell influencers to include sponsorship disclosures clearly and conspicuously (instead telling them to disclose “below the fold”), and required the influencers to promote the game in a positive way and not to disclose any bugs or glitches they found.
- Warner Bros. is barred from failing to make disclosures that content is sponsored, and misrepresenting that the reviews and gameplay videos, are the objective, independent opinions of video game enthusiasts or influencers, and must now educate influencers on sponsorship disclosures, monitor influencer videos, and terminate or withhold payment from influencers or ad agencies for non-compliance.



Medical Expertise

- **FTC v. SmartClick Media LLC**

- FTC filed a complaint alleging that the defendants marketed their “Doctor Trusted” programs to websites that offered health-related products and services but that the seals and certificates were meaningless. The doctors neither evaluated the products nor determined whether the advertising claims for the products were supported.
- The FTC also alleged that SmartClick operated websites that stated they were offering unbiased advice while in reality operating as advertising vehicles.
- The proposed stipulated final order prohibits the misrepresentation of the medical expertise used to evaluate the product or the frequency with which the products are evaluated. It also requires disclosure of anything not written by an objective source and a judgment of \$603,588 suspended upon payment of \$35,000.



Location Tracking

- **United States of America v. InMobi Pte Ltd.**
 - InMobi settled allegations by the FTC that it tracked hundreds of millions of consumers' locations in order to geo-target their advertising.
 - The FTC charged InMobi with a violation of the FTC Act in tracking consumers' locations without notice or consent and with a violation of the Children's Online Privacy Protection Rule for failing to inform parents of these practices or obtaining parental consent prior to information collection.
 - The FTC alleged that InMobi tracked locations regardless of whether the applications using its software asked for consumers' permission, or when they specifically denied it permission to track their location, but that the company represented that its software would only do so when consumers opted in through the device's privacy settings.
 - The agreement called for a judgment of \$4 million, suspended to \$950,000 based on InMobi's financial condition, and a new privacy program.



Certification Deception

- **In the Matter of Very Incognito Technologies, Inc. (d/b/a Vipvape)**
 - FTC approved a final order resolving the Commission’s complaint against Vipvape, under which it is prohibited from misrepresenting its participation, membership, or certification in any privacy or security program sponsored by a government, self-regulatory or standard-setting organization.
 - The complaint alleged that Vipvape deceived consumers about its participation in the Asia-Pacific Economic Cooperation Cross-Border Privacy Rules by stating on its website that it was a participant while not being actually certified to participate.



Withdrawal Remedies

- **FTC v. Sunrise Nutraceuticals**

- Defendants settled FTC charges that it made deceptive and unsubstantiated claims about Elimidrol, a powdered drink mix marketed as treating opiate symptoms and addiction.
- Through online advertisements, Defendants made various claims about the product:
 - “guaranteed to work”
 - “the “#1 opiate withdrawal supplement”
 - “Elimidrol is the difference between just another failed attempt and lifelong success”
 - “turn up the chances of a successful recovery”;
 - “high success rate . . . in overcoming opiate withdrawal”
- The proposed stipulated order requires defendants to substantiate claims about covered products with competent and reliable scientific evidence and to pay \$235,000 for consumer injury and disgorgement, lowered from \$1,398,037 based on Sunrise’s ability to pay.



Pop-Up Advertisements

- **FTC v. Big Dog Solutions**

- The FTC, under the FTC Act and Telemarketing Act, and the State of Florida, under the Florida Deceptive and Unfair Trade Practices Act, filed a complaint for permanent injunction and other equitable relief against Defendants for their alleged use of deceptive advertisements and practices.
- Defendants pressured consumers into buying computer “repairs” and antivirus software. Their internet advertisements were designed to resemble security alerts originating from the computer’s operating system and directed consumers to call a toll-free number. The calls went to a call center at which point Defendants’ telemarketers informed the consumer that they had immediate security risks, ones which they could pay Defendants to resolve.
- Defendants also used chatbots that indicated the support provided was affiliated with Microsoft or Apple, for instance by stating that the chatbot persona is a “Microsoft Certified Partner.”
- The complaint sought a temporary and a preliminary injunction and the Northern District of Illinois issued a temporary restraining order that prevents defendants from charging consumers via credit or debit card, along with an asset freeze, appointment of receiver and other equitable relief.



Lead Generator

- **FTC v. Inbound Call Experts**

- Defendants settled with the FTC and the state of Florida following charges of deceptive practices in their sale of security software and services.
- Defendants were lead generators in a scam involving “free trials” of security software. Software was available for free but would identify a problem in the computer, even if there was none, that required a different, paid version of software to resolve.
- Upgrading software also required calling defendants’ telemarketers who sold unnecessary services through high-pressure sales tactics.
- Settlement requires defendants to perform diligence on current businesses it finds leads for as well as future ones and imposes monetary judgment of \$29,539,628.11, suspended to \$258,000 based on ability to pay.



Multi-Level Marketing

- **FTC v. Herbalife**
- **Defendants settled with FTC over charges that its promotional and marketing activities are misleading.**
- **Herbalife's marketing allegedly expressed that by becoming a distributor, individuals could earn substantial income, enough to replace a full-time job. Videos, events, and print materials all represent that participants will earn substantial income by becoming a Herbalife distributor, but the overwhelming majority of participants make little or no money.**
- **Herbalife also advertises that income is generated through retail sales, which the FTC alleges is untrue, rather substantial income can only be generated through recruiting others to join. FTC**
- **The order requires Herbalife to:**
 - Restructure its compensation system so income is dependent upon individual's retail sales and not on recruiting other distributors to buy Herbalife's products.
 - Stop making misrepresentations concerning the substantial income a Herbalife distributor will obtain, such as claiming individuals can quit their jobs or earn enough for luxury cars.
 - \$200 million judgment for consumer redress.
 - Hire an Independent Compliance Auditor for seven years to ensure compliance with the order's requirements for the new compensation plan.
- **Notably, Herbalife was not labeled a Pyramid or Ponzi scheme in the order.**



Asian-Pacific Economic Cooperative's Cross-Border Privacy Rules

- The FTC sent a warning letter to 28 companies that claim participation in the APEC CPBR without having taken the necessary steps to be able to do so.
- Specifically states that false claims of APEC CPBR involvement can and has previously led to action under Section 5 of the FTC Act.
- Requests that recipients remove the false claims from their websites and notify the FTC within 45 days of their compliance.



FTC Penalty Adjustment

- **FTC Announces Inflation Adjustment of Penalties**
 - In a Federal Register Notice, the FTC announced that the \$16,000 maximum civil penalty will be raised to \$40,000 for violations of sixteen law provisions, including the Clayton Act and Section 5 of the FTC Act.
 - The increased penalties will become effective on August 1 and it will only function prospectively.



Lanham Act Developments

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Lanham Act Cases

- **Handsome Brook Farm LLC v. Humane Farm Animal Care Inc.**
 - Organic egg certification organization sent a letter to various high level individuals at top grocery chain stores asking them to rethink purchasing Plaintiff's eggs for failing certain organic certification requirements.
 - The email was clearly targeted at affecting the purchasing decision of the recipients.
 - To state a claim for relief under the Lanham Act's false advertising provision, defendant's false or misleading statement must be a "commercial advertising or promotion."
 - Interesting issues:
 - Was the email commercial speech?
 - Yes – while the mission of Humane Farm may have been to promote the human treatment of animals, "[t]he Court has little difficulty concluding that speech is commercial when it comes from a speaker whose organizational goal is to direct demand toward certain consumer goods, the speaker receives revenue based on the amount of those goods sold, that revenue is the speaker's largest source of income, and the speech in question directly promotes those same goods while disparaging the goods of a competitor."



Lanham Act Cases

- **Handsome Brook Farm LLC v. Humane Farm Animal Care Inc.**
 - Was the Defendant a competitor?
 - Yes
 - The court reaffirms Lexmark's holding that plaintiff does not need to be a direct competitor of defendant
 - It would make no sense to have jurisdiction to bring the claim, but then fail on the merits because Plaintiff is not a competitor.
 - Sufficient to be a competitor in a different stage of the processing
 - Was the email sent for a promotional purpose?
 - Yes – "Regardless of how Defendant views itself, the economic reality is that HFAC's relationship with egg producers is that of a licensor; its product is a license. It is true that the license promotes a public interest, but it is commercial nonetheless. "
 - Was the speech sufficiently disseminated?
 - Defendant argued that it was only sent to certain grocery stores, not sufficient.
 - The court disagreed saying: "Defendant, however, fails to bolster its argument with any authority for the position that a targeted advertisement is not an advertisement."
 - The 69 recipients represented the top ten conventional grocery chains nationwide (over 16,000 stores)



Lanham Act Cases

- **Handsome Brook Farm LLC v. Humane Farm Animal Care Inc.**

- False Advertising Analysis:

- False or Misleading Descriptions of Fact? Yes.

- The Email contained several false or misleading statements w/in the commercial promotion:

- » Producers' eggs were not pasture raised = FALSE → Each of the 3 farms underwent and passed AHA audits in Dec. 2015 such that they can be labeled American Human Certified™ pasture raised.
- » *A whistleblower complaint caused Defendant to send an auditor to inspect Plaintiff's packing plant* = FALSE → The complaint was unrelated to the audit.
- » *No annual certification update is on file / our auditors found that the organic certification was not current* = This language creates the FALSE impression that the Plaintiff's eggs are being mislabeled as certified organic.

- Materiality? Yes.

- Consumers in the ethically sourced egg market, including retailers, are concerned with whether eggs are certified.
- Defendant's own business model is based on the idea that consumers (and retailers and producers) will find the certifications material.

- Deception and Injury? Yes.

- The speech promotes the Plaintiff's goods while disparaging Defendant's goods.
- This case contains literally false statements, so external evidence is not needed. Regardless, there is evidence of actual deception.
 - » One recipient of the email withdrew Plaintiff's eggs from its shelves indefinitely; one regional retailer temporarily suspended sales of the eggs; and one retailer delayed launching Plaintiff's eggs at its stores.



Lanham Act Cases

- **Smart Vent Inc. V. U.S. Floodair Vents Ltd.**

- Plaintiff moved for summary judgment on its patent infringement and unfair competition claims against Defendant for falsely advertising its flood vents as FEMA, ICC, and NFIP certified.
 - Defendant argued that Plaintiff could not demonstrate falsity because “licensed, professional engineers have confirmed that the vents exceed the [actual] requirements of the NFIP[.]”
 - Plaintiff argued that the relevant regulations require an Evaluation Report issued by the International Code Council Evaluation Service (ICC-ES), not an individual certification.
- Holding
 - Plaintiff offered sufficient evidence for a finding of falsity and that the claim was made in interstate commerce.
 - HOWEVER - the Court also found that Plaintiff put forth **no evidence** to support a finding of a likelihood of deception and injury as a result of the false statements.
 - “Smart Vent adduces no facts to demonstrate satisfaction of this element. Indeed, Smart Vent makes no mention of the term “deception” in any portion of its 125-paragraph statement of material facts. “
 - The lesson here is to be sure to focus on all elements of the Lanham Act claim when on summary judgment, not just falsity.



Lanham Act Cases

- **De Simone v. VSL Pharmaceuticals, Inc.**
 - VSL moved for a preliminary injunction on its false advertising claim alleging that De Simone and its probiotic manufacturer falsely advertised that VSL#3 is no longer on the market or that Visbiome is the rebranded version of VSL#3.
 - VSL moved for Preliminary Injunction based on two statements:
 - (1) VSL identified a statement on the Visbiome website, “Message From the Inventor” stating:
 - “Recently, I made the decision to end my long-term partnership with VSL Pharmaceuticals, Inc., the company for which I collaborated for many years to produce and market the De Simone Formulation under the trademark, VSL#3 . . . I am pleased to announce that my formulation is now exclusively available from ExeGi Pharma under the trademarks Visbiome and Visbiome Extra Strength.”
 - (2) VSL identified statements made by 2 ExeGi sales representatives at 3 doctor’s offices, falsely suggesting that VSL#3 was no longer on the market.



Lanham Act Cases

- **De Simone v. VSL Pharmaceuticals, Inc.**
 - Issues
 - Whether the exclusivity statements made on Visbiome’s website that the De Simone Formulation is exclusively available through ExeGi is likely to succeed on the merits.
 - The Court found the above statement to likely be literally false because it is uncontested that VSL continued to purchase VSL#3 from another manufacturer when VSL’s Agreement with De Simone expired. Thus, for the Visbiome website to assert that the De Simone Formulation was exclusively available through ExeGi is literally untrue.
 - The Court enjoined the advertising claim finding that it was material, was made in interstate commerce (website) and that VSL would suffer harm as a result of the false advertising.
 - The Court presumed deception because the claim was literally false.
 - Whether misleading and/or false statements made by the sales representatives constitute “commercial advertising or promotion” under the Lanham Act.
 - The Court **denied** PI on statements made by ExeGi sale representatives because the evidence is not sufficient to establish a likelihood that VSL can successfully claim that the sales representatives’ statements occurred in “commercial advertising or promotion” as required by the Lanham Act, 15 U.S.C. 1125(a)(1)(B).
 - » If there is a nationwide marketplace, an “isolated” misrepresentation directed at one potential customer will not constitute “commercial advertising or promotion.”
 - The Court’s holding highlights the fact intensive nature of the inquiry into whether a statement constitutes commercial speech or advertising. Other cases exist where statements made by sales representatives have been held to be commercial advertising.



Lanham Act Cases

- **Blue Buffalo Co. v. Nestle Purina Petcare Co.**
 - Blue Buffalo moved to dismiss Purina’s counterclaims which alleged that Purina falsely advertised its pet food brands by misleading consumers into thinking certain ingredients were primary ingredients when they were not, and suggesting that certain ingredients were premium ingredients when they were of inferior quality.
 - The Court held that most of Purina’s claims “bordered on frivolous”, but because some required the evaluation of extrinsic evidence, the claims survived 12(b)(6).
 - It is interesting to see which claims the court felt extrinsic evidence is required and which claims the court decided without allowing for extrinsic evidence.
 - **Product Claims**
 - **Super 7 LifeSource Bits**
 - Purina alleged that Blue Buffalo falsely advertised this product as superior in nutrition to other pet foods, and that the products contain a significant amount of the certain ingredients. Example: A graphic appears on the product packaging, depicting certain fruits and vegetables. The packaging also contained the statement “healthy fruits & veggies.” However, these ingredients likely only make up 0.25% of the product overall.
 - Sufficient to survive 12(b)(6).



Lanham Act Cases

- **Blue Buffalo Co. v. Nestle Purina Petcare Co.**

- Product Claims cont'd

- Savory Sizzlers

- Purina alleged that Blue Buffalo falsely advertised this product as containing bacon as a main ingredient when, in fact, it does not contain any bacon.
- The only mention of bacon is on the back of the packaging, in small lettering, “if there’s one thing that will bring dogs running, it’s the smell of bacon sizzling in the pan. Tasty BLUE Sizzlers are the naturally healthy alternative to the real thing[.]”
- Dismissed, finding no reasonable consumer would believe the product contains bacon as a main ingredient when the packaging clearly states pork or chicken as the first ingredient. Further, the bacon statement is about the product being an alternative to bacon.

- Health Bars

- Purina alleged that Blue Buffalo falsely advertised its Health Bars as containing certain primary ingredients when in fact those ingredients are not primary (i.e. Health Bars Baked with Banana and Yogurt, Health Bars Baked with Bacon, Egg & Cheese).
- Dismissed, finding reasonable consumers know, as a fact of life, that biscuits are not composed primarily of fruit and yogurt, but rather, like all baked goods, are primarily composed of grains and flours.

- Family Favorite Recipes

- Purina challenged the packaging and advertising of Blue Buffalo’s following flavors: Mom’s Chicken Pie, Shepard’s Pie, Turducken, etc. The packaging for these flavors depict images of the traditional dish, allegedly misleading consumers into thinking the pet food contains human-grade meals comprised of identical ingredients (i.e. Mom’s Chicken Pie flavor does not actually contain any pie crust or wheat)
- Dismissed, finding no reasonable consumer would expect dog food to contain whole turkeys, turduckens, or pies.



Lanham Act Cases

- **Blue Buffalo Co. v. Nestle Purina Petcare Co.**

- Product Claims cont'd

- Wild Bones

- Purina alleged that Blue Buffalo's Wild Bones Dental Chews misleads consumers into thinking the product contains actual bone, when in fact it does not. Specifically, Purina alleged that the bones are in the shape and color of "true bones," which are visible through the packaging, and that the product comes from Blue Buffalo's "Wilderness" product line, giving consumers the impression that it contains real bones.
- Dismissed, finding no consumer would believe it's real bones. Contrary to Purina's assertions, the bones are in the shape of cartoon bones, sized like a dog biscuit, with the word "WILDERNESS" embossed.

- Healthy Gourmet Flaked Fish & Shrimp Entrée

- Purina alleged that this product misled consumers into believing that the product is "comprised primarily of wholesome seafood and shrimp."
- The ingredient list shows that shrimp is only the 8th ingredient. However, "ocean fish" and "fish broth" are listed as the 1st and 2nd ingredients, respectively.
- Shrimp claim is sufficient to survive 12(b)(6), finding that reasonable consumers may believe the product contains more shrimp than it actually does.
- Wholesome seafood claim dismissed because consumers would have to disregard well-known facts of life to believe it.



Lanham Act Cases

- **Enigma Software Group USA v. Bleeping Computer LLC**

- Enigma Software Group (ESG) makes computer security products, notably SpyHunter, which is an anti-malware program. It alleges that a Bleeping forum moderator, here called a “staff member,” made comments on Bleeping’s website’s forum directing readers not to use SpyHunter or ESG because it’s an inferior product. The moderator would instead suggest a different product that Bleeping receives commissions from.
- ESG alleges that Bleeping’s actions constitute false and defamatory statements that amount to false advertising and violate the Lanham Act.
- Considering Defendant’s motion to dismiss, the Court finds that the Communications Decency Act does not apply to the Lanham Act and that a six-year fraud statute applies to false advertising claims.
- The Court also found that ESG adequately pled its claim for false advertising.
 - Defendant’s actions could arise to commercial advertising or promotion because Bleeping was allegedly suggesting replacement of ESG’s products with a product Bleeping promotes.
 - The dissemination requirement may be met by the allegation that any new inquiry on the forums was met with negative comments about SpyHunter and ESG.



Lanham Act Cases

- **Nutrition Distribution LLC v. Custom Nutraceuticals LLC**
 - Plaintiff claims Defendants have engaged in false advertising of its product Ostarine, which is a “selective androgen receptor modulator” and is similar to anabolic steroids.
 - Defendants allegedly labeled Ostarine as “not for human consumption,” while also marketing it as a body-building drug and an “easy to dose oral SARM.”
 - Defendants allegedly failed to disclose that Anti-Doping agencies have banned SARM’s, which would be relevant to competing bodybuilders and athletes who use this type of product.
 - As part of its motion to dismiss, Defendants argued that the FDA has primary jurisdiction to determine if Ostarine is safe, but the Court denied the motion to dismiss because the Defendants’ claims about the drug is at issue, not only the drug’s safety.



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State AGs

- **In the Matter of Advanced Social Media, LLC**
 - Arizona AG shut down fraudulent Grant Funding Training Business.
 - Company accused of making false promises to organizations seeking grants agreed to shut down after consumer fraud investigation into allegations of false advertising with promises of grant funding.
 - The company made false statements and misrepresentations regarding effectiveness in order to sell grant funding training tools and social media advertising, telling consumers their chances of receiving grant dramatically increased by purchasing their trainings and misled consumers by greatly exaggerating social media reach.
 - Company will cease operations and file paper to terminate its LLC in Assurance of Discontinuance.



State AGs

- **NY AG Declares Trump University is Fraudulent**

- NY AG commented on the Trump University suit, stating, “We have laws against running an illegal, unlicensed university. This never was a university. The fraud started with the name of the organization.”
- Initial estimates place Trump at “pocket[ing] \$5 million,” while Trump counters that the NY AG is bringing the suit for political purposes. Schneiderman, the NY AG, sits on the side of Hillary for New York Leadership Council.
- The AG has stated that if Trump becomes President, he could still be called to testify.



State AGs

- **Minnesota Attorney General Sues Magazine Sales Company over Alleged Deception**
 - Minnesota Attorney General Lori Swanson filed suit against Your Magazine Service and its owner for targeting seniors with packages costing nearly \$1,000 and falsely informing non-customers that they are calling to provide a billing credit on an existing account.
- **Arkansas AG Releases Statement after Meeting with CFPB Director**
 - Arkansas AG encourages conference of states to discuss the proposed federal standards for credit lines, installment loans, deposit advances, automobile-title secured loans and payday loans.



State AGs

- **State of Michigan v. Veolia and LAN**
 - Michigan Attorney General Bill Schuette filed a complaint alleging that Veolia North America Inc. and Lockwood Andrews & Newnam Inc. contributed to the water crisis in Flint, Michigan, stating that the companies had “botched the work they were hired to perform related to Flint’s drinking water.”
 - The complaint seeks a judgment in excess of \$25,000, but at the news conference Schuette indicated the damages could be in the hundreds of millions of dollars.
- **Jimmy John’s Settlement**
 - New York AG Eric Schneiderman announced that Jimmy John’s would stop including sample non-compete agreements in hiring packets it sends to its franchise locations. The Attorney General concluded that such non-compete agreements are unlawful and may not be used by the chain.
 - The noncompete agreements prohibited sandwich makers from working at any establishment within a two-mile radius of Jimmy John’s that made more than 10% of its revenue from sandwiches.



State AGs

- **Boston Grand Prix Ticket Refunds**

- The Massachusetts Attorney General’s office filed a complaint against Boston Grand Prix (BGP) for soliciting and selling tickets with a written guarantee of a full refund in the event of cancellation when it could not cover pre-event costs without using the ticket deposits.
- BGP refunded only \$400,000 of \$2,086,798.67 purchases.

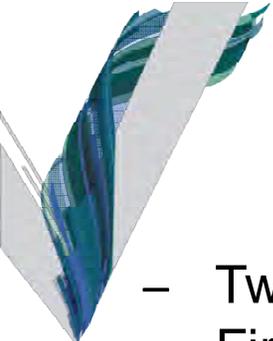


FDA Developments

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FDA

Final Rules: Nutrition Labeling & Serving Size Rules

- Two final rules published May 27, 2016
- First significant change to nutrition labeling rules in 20 years
- **Compliance date:** July 26, 2018, small business = July 26, 2019
- Changes to BOTH conventional foods and dietary supplements
- Significant changes include:
 - Added sugars declaration
 - New definition of “dietary fiber”
 - Changes to RDIs & DRVs
 - Declaration of vitamin D & potassium required on foods
 - Declaration of vitamins C, A no longer mandatory on foods
 - Created RDI for choline and fluoride
 - 2-year recordkeeping requirement
 - Dual column labeling
 - Serving size changes

FDA Final Rules: A New Look

Original Label		New Label	
Nutrition Facts Serving Size 2/3 cup (55g) Servings Per Container About 8		Nutrition Facts 8 servings per container Serving size 2/3 cup (55g)	
Amount Per Serving Calories 230 Calories from Fat 72		Amount per serving Calories 230	
	% Daily Value*		% Daily Value*
Total Fat 8g	12%	Total Fat 8g	10%
Saturated Fat 1g	5%	Saturated Fat 1g	5%
Trans Fat 0g		Trans Fat 0g	
Cholesterol 0mg	0%	Cholesterol 0mg	0%
Sodium 160mg	7%	Sodium 160mg	7%
Total Carbohydrate 37g	12%	Total Carbohydrate 37g	13%
Dietary Fiber 4g	16%	Dietary Fiber 4g	14%
Sugars 1g		Total Sugars 12g	
Protein 3g		Includes 10g Added Sugars	20%
Vitamin A	10%	Protein 3g	
Vitamin C	8%	Vitamin D 2mcg	10%
Calcium	20%	Calcium 260mg	20%
Iron	45%	Iron 8mg	45%
<small>* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.</small>		Potassium 235mg	6%
Total Fat	Less than 65g	<small>* 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.</small>	
Sat Fat	Less than 20g		
Cholesterol	Less than 300mg		
Sodium	Less than 2,400mg		
Total Carbohydrate	300g		
Dietary Fiber	25g		
	30g		

Vitamins A & C no longer required

Serving size prominence

Calories – type size & bold

Added sugar declaration

Vitamin D & Potassium

DV footnote revised

FDA Final Rules: Supplement Facts Label

Old Version

New 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.

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.





FDA

Final Rules: Supplement Facts Label

Supplement Facts

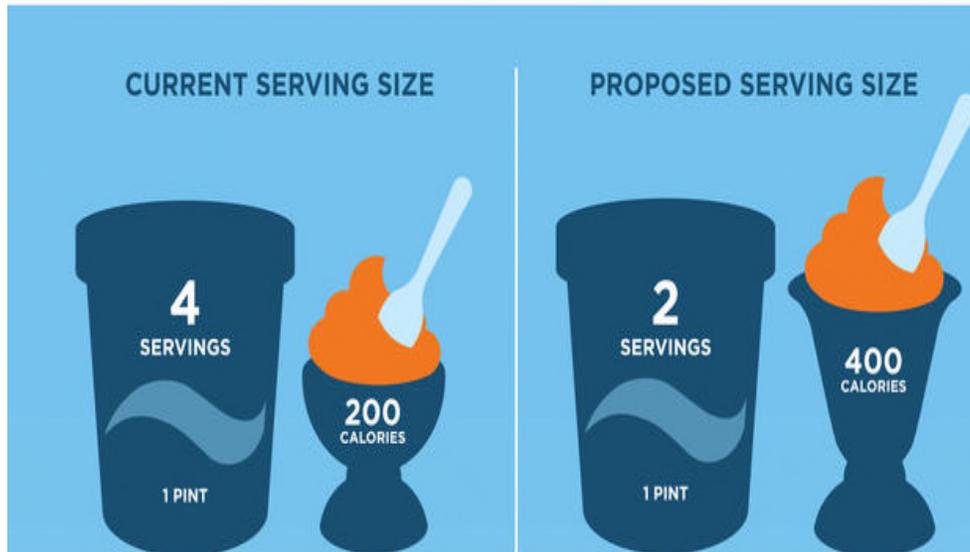
Serving Size 1 Packet
Servings Per Container 10

Amount Per Packet	% Daily Value	Amount Per Packet	% Daily Value
Vitamin A (from cod liver oil)	900 mcg 100%	Zinc (as zinc oxide)	11 mg 100%
Vitamin C (as ascorbic acid)	250 mg 278%	Selenium (as sodium selenate)	25 mcg 45%
Vitamin D (as ergocalciferol)	20 mcg 100%	Copper (as cupric oxide)	0.5 mg 56%
Vitamin E (as di-alpha tocopherol)	75 mg 500%	Manganese (as manganese sulfate)	5 mg 217%
Thiamin (as thiamin mononitrate)	60 mg 5000%	Chromium (as chromium chloride)	50 mcg 143%
Riboflavin	60 mg 4615%	Molybdenum (as sodium molybdate)	50 mcg 111%
Niacin (as niacinamide)	60 mg 375%	Potassium (as potassium chloride)	10 mg <1%
Vitamin B ₆ (as pyridoxine hydrochloride)	60 mg 3529%	Choline (as choline chloride)	100 mg 18%
Folate	400 mcg DFE 100%		
	(240 mcg folic acid)	Betaine (as betaine hydrochloride)	25 mg *
Vitamin B ₁₂ (as cyanocobalamin)	100 mcg 4167%	Glutamic Acid (as L-glutamic acid)	25 mg *
Biotin	100 mcg 333%	Inositol (as inositol monophosphate)	75 mg *
Pantothenic Acid (as calcium pantothenate)	60 mg 1200%	<i>para</i> -Aminobenzoic acid	30 mg *
Calcium (from oystershell)	130 mg 10%	Deoxyribonucleic acid	50 mg *
Iron (as ferrous fumarate)	10 mg 56%	Boron	500 mcg *
Iodine (from kelp)	150 mcg 100%		
Magnesium (as magnesium oxide)	63 mg 15%		

* Daily Value not established.

Other ingredients: Cellulose, stearic acid, and silica.

FDA Final Rules: Serving Size



- Serving sizes are expressed in terms of Reference Amount Customarily Consumed (RACC)
- FDA changed RACC for ice cream, yogurt and carbonated beverages to better reflect the amount a typical consumer eats/drinks
- Any product containing between 200%-300% of the RACC must display dual labels, one "per serving" and one "per unit/package"



FDA

Guidance: Sodium Reduction Initiative

- **Sodium DV changed (lowered) in new labeling rule**
- **June 1 Activities:**
 - Draft Guidance: Voluntary Sodium Reduction Goals
 - Webinar and other statements from CFSAN Director
 - Responded to Citizen Petition: maintaining that salt is GRAS and rejected proposal to set mandatory sodium limits in processed foods
- **Guidance applies to food manufacturers, restaurants and food service operations**
- **Quantitative goals for 150 food categories in the short term (2 years) and long term (10 years)**



FDA

Proposed Rule: OTC Antiseptic Rub Products - Tentative Final Monograph

- Published June 30, 2016
- Requesting updated data to determine whether active ingredients are GRASE before FDA will finalize the monograph
- 3 ingredients included in in current TFM will not be GRASE in final monograph without new supportive data
- FDA requests *in vitro* and *in vivo* clinical simulation studies, log reduction data and use factors data





FDA

Final Rule: Use of Symbols on Device Labels

- Final Rule: June 15, 2016
- Allows stand-alone graphics/symbols without adjacent explanatory text under certain circumstances
- Intended to harmonize global labeling requirements to alleviate burden on manufacturers
- Symbols must be recognized by FDA or another standards organization
- Different requirements apply depending on whether the symbol is FDA-recognized
- “Rx only” officially permitted in lieu of longer prescription statement



FDA

Enforcement: Soy Sauce Consent Decree

- The U.S. District Court for the Eastern District of California entered a consent decree of permanent injunction between the FDA and Wa Heng Dou-Fu & Soy Sauce Corp. requiring the business to immediately cease manufacturing and distributing food until it has complied with federal food safety laws.
- The FDA documented violations including inadequate hand washing, improperly cleaned equipment, and failures to adequately protect against contamination. The FDA also found positive examples of salmonella. No illnesses have been reported in connection with the corporation.



Federal Developments: CFPB

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CFPB

- **CFPB v. Intercept Corporation**

- CFPB alleges defendants, Intercept Corporation and its executives, willfully ignored fraud by its clients, including unconscionably high rates of return payments due to withdrawals, insufficient funds, or invalid accounts.
- CFPB alleges defendants violated the Dodd-Frank Wall Street Reform and Consumer Protection Act's prohibition against unfair acts and practices by processing payments for clients without adequately investigating, monitoring, or responding to red flags indicating clients were breaking the law and deceiving customers. Intercept provided access to the system to extract money from consumers' bank accounts.



CFPB

- **New “Auto Loan Shopping Sheet”**
 - Sheet helps consumers see the total cost of an auto loan, gives “apples to apples” comparisons of loan products, and helps them pick the right financing for their situation.
 - New tools are live here: <http://www.consumerfinance.gov/consumer-tools/auto-loans/>
- **CFPB Proposal affecting Payday Loan Companies**
 - 1,300 page proposal would require, payday, auto title and other lenders to confirm a borrower’s ability to repay loans and restrict renewals of small-dollar loans.
 - No exemption for underwriting standards using a proposed “payment-to-income” test, meaning banks will still avoid giving payday loans.
 - The proposed rule attempts to attack them by forcing lenders to check a consumer’s ability to repay the loans in full without the need to re-borrow, as well as their ability to pay expected expenses like rent, utilities and child care. The bureau would also limit to three the number of times a loan can be rolled over and put limits on collection practices.



CFPB

- **CFPB Supervisory Action Returns**

- The CFPB has returned \$24.5 million to 257,000 customers from January to April 2016, it announced. These payouts resulted from enforcement actions against deceptive auto loans, incorrect sale of accounts to debt collectors, and misleading consumer information about debt repayment options.

- **CFPB Proposed Rule: Amendment to the Annual Privacy Notice Requirement Under the Gramm-leach-Bliley Act (Regulation P)**

- The current rule requires financial institutions to provide an annual notice describing their privacy policies and practices to their customers. This proposal provides an exception to the annual notice requirement in certain cases.

- **CFPB Enforcement against BancorpSouth Bank**

- The CFPB and the DOJ announced a joint action against BancorpSouth Bank for discriminatory mortgage lending. If the proposed consent order is approved, Bancorp will pay \$10.6 million to address the discriminatory practices.



NAD Developments

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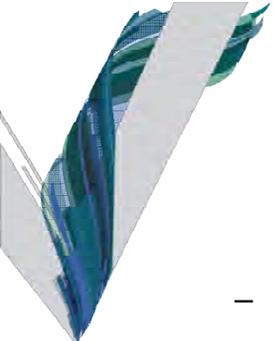
NAD

Applegate Insulation, Case #5961

- Challenger: North American Insulation Manufacturers Association (fiberglass manufacturer)

- Select Claims:
 - “Applegate Cellulose Insulation can reduce your utility bill by up to 40%.”
 - “Fire retardant additives used to manufacture Applegate are non-toxic. One of the additives, boric acid, is six times less toxic to humans than table salt.”
 - “Pound for Pound Applegate Cellulose Insulation is more effective at reducing energy costs than glass....”
 - Applegate’s cellulose products are superior to all fiber glass insulation. [implied claim.]

- NAD Recommended:
 - Discontinue comparative claims for the company’s cellulose insulation products; “R-value per inch” claims may persist.
 - NAD determined that “studies” may imply consumers will experience the same energy savings as reported in these studies, which the studies’ designs did not support.
 - Applegate acquiesced and will change its advertising.



NAD

Reckitt Benckiser, LLC, Case #5942 (Compliance Report)

- **Challenger: The Proctor & Gamble Company**
- **Claim: “Best Buy” Claim**
 - “Rated Best Buy 3 Years in a Row*”
 - *Finish Powerball All in 1 was rated Best Buy by a leading Consumer Magazine in 2011, 2012, and 2013.
 - Claim allegedly was misleading to consumers in that it suggested Finish Powerball was rated number 1 for the past three years, was the top performing detergent, and was still the top rated detergent.
 - Parties agreed claim would be discontinued. For compliance purposes, the NAD views voluntarily discontinued claims as though the NAD recommended their discontinuance.
- **Issue: Is Reckitt Benckiser, LLC (“Advertiser”) out of compliance with a prior agreement with Proctor & Gamble (“P&G”) through NAD to cease using the Best Buy claim?**
 - Advertiser allegedly continued to display the claim in Safeway and Costco Displays as recently as May and June of 2016. The most recent displays featured an array of Advertiser’s products, further misleading consumers into thinking all Advertiser’s products were top rated.
- **NAD Finding: Advertiser remains in compliance for the following reasons:**
 - Advertiser shipped no new product with the Best Buy claim after the claim was discontinued. Advertiser explained that these store locations used incorrect product pallet rotations or were simply taking longer to sell the product sent to them prior to the claim’s discontinuance;
 - Advertiser agreed to contact the stores where the displays are posted to ensure they are taken down in a timely fashion; and
 - Advertiser agreed to take affirmative action to ensure Best Buy claims would not appear in stores, even if on older, pre-discontinued merchandise.



NAD

Verizon Communications, Inc., NARB Panel #209

- **Challenger: Comcast Cable Communications**
- **Claim: “#1” Claim**
 - “In customer satisfaction studies FiOs is rated #1 in internet speed...8 years running.”
 - “TV service rated number one in HD picture quality...based on consumer satisfaction surveys.”
 - In PC magazine’s Readers’ Choice Survey, Verizon FiOS received the highest rating in customer satisfaction with respect to Internet speed, but the ranking was not based on a comparison of objective performance or a head-to-head comparison.
- **NAD Finding: The claims communicated a product superiority message in terms of actual speed and quality rather than customer satisfaction and should be discontinued.**
 - Verizon appealed.
- **NARB Finding: Advertiser should modify their #1 claims for Internet and television service to more clearly communicate the basis for the claims.**
 - The NARB recommended that the first challenged advertisement be modified to communicate that the rating is a customer satisfaction rating based on consumers’ rating of their own Internet providers.
 - The NARB similarly recommended that the second one should also be modified to communicate the basis more clearly as customer satisfaction ratings rather than objective performance.



NAD

Advanced Nutritional Innovation, Inc. Case #5959

- Challenger: Council for Responsible Nutrition
- Select Claims:
 - “Protect the body against damaging radiation!”
 - “ionDEFENDER provides protection by dramatically boosting the body’s powerful natural protection.”
 - “It provides protection for: people living in areas contaminated by nuclear disasters, meltdowns, and leaks; airline pilots and crew exposed to high energy cosmic radiation and solar radiation; people concerned about exposure to microwave radiation (WiFi/cellphone).”
 - Asserted that ionDEFENDER supplements elevate superoxide dismutase (SOD) levels, protecting the body from damaging ionizing radiation and a variety of health conditions.
- NAD Finding: Advertiser should discontinue most of its claims as unsubstantiated.
 - NAD found that the advertiser provided no evidence addressing effects on illness or damage caused by nuclear disasters, cosmic radiation, or non-ionizing radiation, and only anecdotal evidence regarding effects on hangovers.
 - The medical literature reviews and in vitro and animal studies also failed to provide a reasonable basis for any of the damage/disease protection, aging, radiation, and hangover claims, or demonstrate a consensus on the health benefits of this sort of supplementation generally.
 - Allowed the claim that “SOD plays the primary role, transforming the most dangerous free radicals, the superoxide radicals, into ions that are less reactive. These are further transformed by Catalase and glutathione peroxidase” because it was merely descriptive.



NAD MyGait, LLC

- Challenger: None, part of routine monitoring practice. Claims were featured in AARP Bulletin.
- Select Claims:
 - “The failure-free, worry-free computer designed just for seniors.”
 - “The MyGait Senior Computer includes a highly personal U.S.-based support network, available through the build-in HELP on MyGait or via telephone by toll-free call. . . .” [no disclaimer of monthly charge]
 - “Lifetime Unlimited Support** **Computer includes a worry-free \$19.95 monthly service program”
 - “Out-of-box setup in just 15 minutes.”
- NAD Finding: Advertiser should discontinue certain claims and modify others.
 - NAD recommended that MyGait modify its advertising to make clear that the computer itself and the service associated with the “worry-free” claims are separate purchases. MyGait should clearly state that for the “worry-free” aspects, consumers would need to purchase the computer and the service package.
 - NAD determined the “designed for seniors” claim is supported but recommended the “just 15 minutes” claim be modified to disclose that quick set up requires connection to the internet.
 - NAD recommended MyGait discontinue the unsupported claim that the computer “does everything a costly complicated computer does.”



Class Actions

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Class Actions

- **Williams v. Sun Products Corp. (S.D.N.Y.)**
 - Putative class action alleging liquid detergent packages are oversized to mislead consumers into thinking they receive more detergent than they are.
 - Complaint alleges at least 17% empty space in containers, and that such deceptive packaging was routine to deceive consumer into purchasing a greater volume of detergent at a premium price.
 - Asks court to award unspecified damages reflecting the money lost as a result of the misleading marketing.



Class Actions

- **Dyan D'Aversa v. Playtex Products LLC et. al. (D.N.J.) and Lauren Birmingham v. Edgewell Personal Care Co. et. al. (C.D. Cal.)**
 - Putative class action alleging that defendants knowingly claim on their product labels that the sunscreen offered more than six times the sun protection than they actually do. Both suits contend that the sunscreen marketed as SPF 50 is actually SPF 8, below the minimum recommended SPF of 30.
 - A similar case alleging that Playtex and Sun Pharmaceuticals were falsely marketing Banana Boat-brand sunscreens with SPFs up to 110 as superior to SPF 50, despite the FDA's finding that they offered no additional protection, settled in 2014.



Daily Fantasy Sports

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Background

- **Since October 2015, various states have sought to address Daily Fantasy Sports.**
- **New state laws, Attorney General Opinions declaring DFS to be illegal gambling.**
 - Alabama, Georgia, Hawaii, Idaho, Illinois, New York*, Nevada*, South Dakota, Texas, Vermont and Delaware
- **Other states have proposed/adopted legislation legalizing/regulating DFS**
 - Rhode Island, Massachusetts, Maryland regulations
 - Colorado, Indiana, Mississippi, Missouri, New York (awaiting signature)*, Tennessee, Kansas and Virginia





State Legislation

- **Most common provisions in States allowing DFS**
 - Minimum age of 18
 - Prohibition on employee participation
 - Prohibition on contests involving college or amateur sports
- **Other common provisions**
 - Yearly audits
 - Licensing fees
 - Segregation of user and operational funds
 - Partnerships with existing gaming establishments
 - Creation of an oversight committee or board
 - Non-deceptive advertising





New York

- **Legal battle between NY AG, DraftKings & FanDuel on hold; settlement agreement now expires July 30th**
- **DraftKings and FanDuel NY operations are currently suspended**
- **New York Bill passed on June 18, 2016, not yet signed by Governor Andrew Cuomo.**





New York

- **Under the Bill (S 5302C):**

- Users must be at least 18 years old.
- Operators must pay both a tax on 15% of their gross revenue generated in New York and an annual tax of 0.5% (not to exceed \$50,000).
- Advertising must accurately represent chances of winning, and cannot target children.
- Must offer introductory procedures for all levels of players and allow players to identify a highly experienced player before playing them.
- Requires information be provided to consumers on the risk of compulsive play.
- Operators must safeguard the privacy and online security of players.
- No DFS games related to college or high school sports may be offered.



Colorado

- **HB 1404 signed into law on June 10, 2016**
 - Oversight by the Division of Professions and Occupations in the Department of Regulatory Agencies
 - The DPO is responsible for setting licensing and renewal fees; those figures are not set in the law.
 - Operators with less than 7,500 users must only register with the state, they need not apply for a license.
 - Operators that are not classified as “small” must contract with a third party to perform an annual audit.
 - prohibition on play by operator employees;
 - data that could affect contests must be secure;
 - Segregation of player funds from operating funds;
 - Must allow players to restrict themselves from playing.
 - Amateur and College sporting contests are prohibited.
 - Users must be 18 years old to play.
 - Fantasy contests may also be offered “at licensed gaming establishments, class B horse racing tracks, and at a licensed facility at which pari-mutuel wagering may occur.”
 - The law takes effect August 10



Other Recent Developments

- **Delaware**

- On July 8, 2016, the Delaware Department of Justice announced that fantasy sports offering cash awards constitute illegal gambling under state law
- Fantasy Sports sites operating in the state have officially been ordered to cease operations in the state.

- **Mississippi**

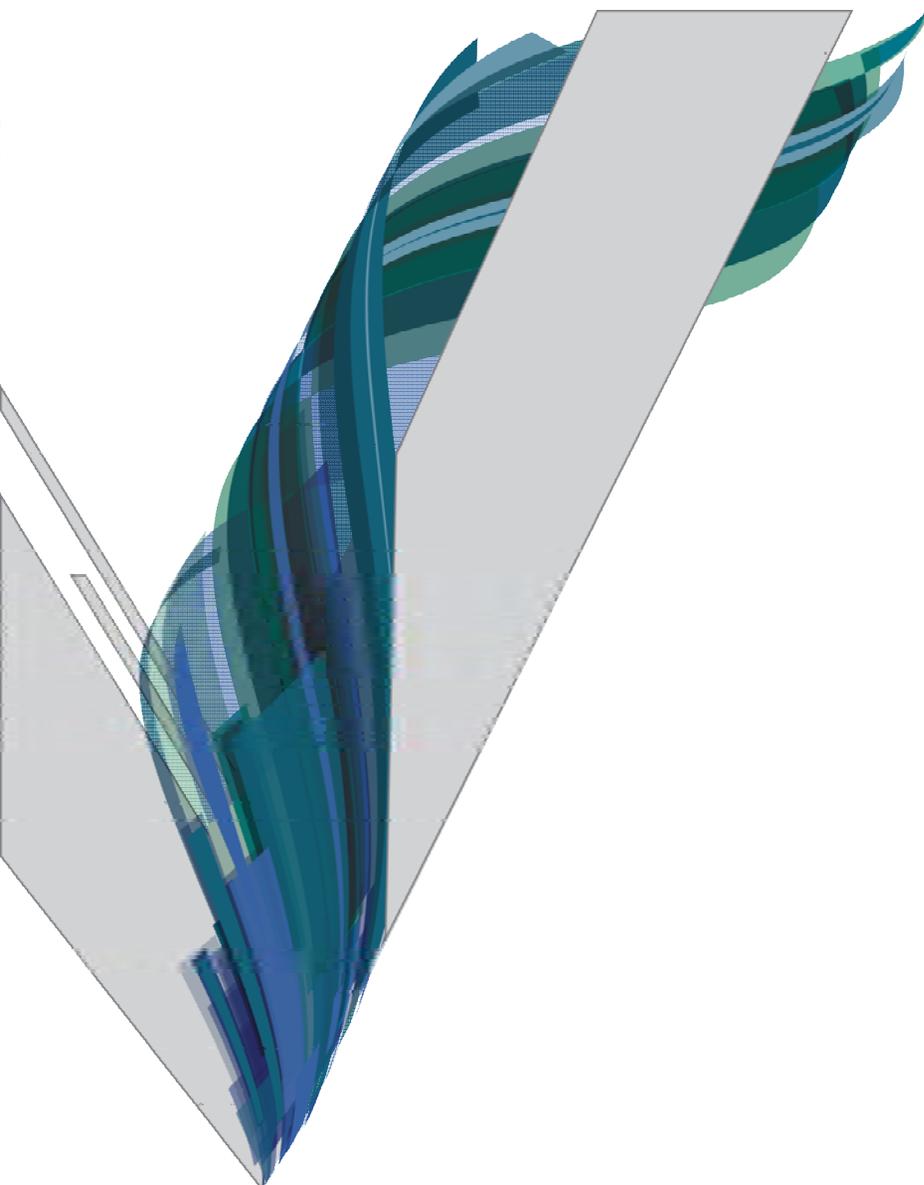
- Senate Bill 2541, signed into law in May legalizing and regulating DFS, went into effect on July 1, 2016.
-

- **Massachusetts**

- Daily Fantasy Sports Rules established by Massachusetts Attorney General Maura Healey went into effect July 1, 2016.

- **Pennsylvania**

- On June 28, 2016, Pennsylvania's House of Representatives passed HB 2150, a bill authorizing online gambling and daily fantasy sports.
- The Bill has yet to pass the state's Senate as of 7/7/2016. Vote not likely until the fall.



VENABLE

QUESTIONS?

July 21, 2016