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Latest Updates on State and Federal Regulations

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Recent Developments We'll Discuss

- Recent Developments at the FDA
  - Meeting to Discuss DSHEA NDI List
  - New Nutrition Labeling Rule Updates
  - GRAS Guidance
  - FSMA Implementation
  - Homeopathic Drugs
  - Kratom
  - Cannabidiol (CBD)
  - Health Claims
    - Soy Protein and Heart Health
    - Peanut Exposure in Infancy
  - Vitamin D Tests
  - FDA Enforcement Trends
- Recent Developments at the USDA
- Recent Developments at the FTC
- Recent Developments with State Attorneys General
- California Proposition 65 Updates

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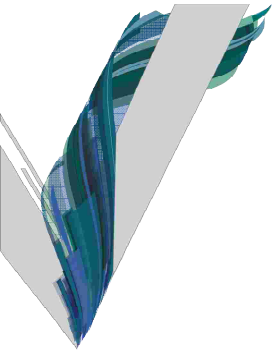


THE FOOD AND DRUG ADMINISTRATION: RECENT DEVELOPMENTS

Public Meeting on "Grandfathered" Dietary Ingredients

- On October 3, the FDA held a public meeting to discuss the development of a list of pre-DSHEA dietary ingredients
  - The purpose of the meeting was to give interested stakeholders an opportunity to discuss issues related to FDA's planned development of a list of pre-DSHEA ingredients
  - Topics included:
    - What evidence is necessary to show that an ingredient was marketed before October 15, 1994?
    - What process should be used to develop the list?
- A recording of the sessions and a transcript of the meeting are available on the FDA website
- FDA accepted comments on the public meeting from September 6 through December 4, 2017

Nutrition Labeling Rule Compliance Date

- In May 2016, FDA issued final rules to implement changes to the nutrition labeling and serving size regulations
  - Mandatory compliance with the new nutrition labeling requirements for food products was initially slated for July 26, 2018 (or July 26, 2019 for manufacturers with less than $10 million in annual food sales)
- In June of 2017, FDA announced that the compliance dates for the new nutrition labeling requirements will be extended
  - Commissioner Gottlieb assured the Senate Appropriations Subcommittee that although the Nutrition Facts label rule is being delayed, FDA has no plans to reopen the rule
  - The Commissioner explained that the delay was implemented simply as a means to carve out additional time to develop and provide "additional guidance to sponsors on how to interpret aspects of the new Nutrition Facts label"
- In October of 2017, FDA proposed to extend compliance dates by 1.5 years

Nutrition Labeling Guidance

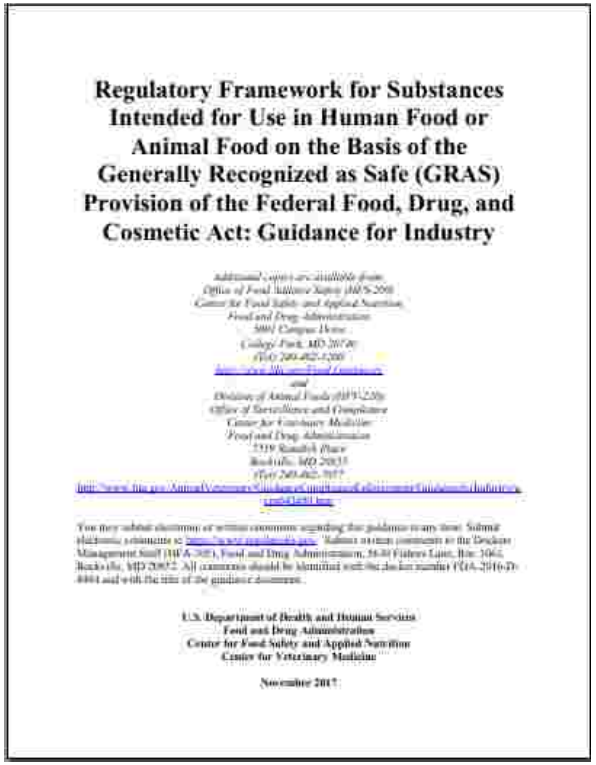
- Last week, the FDA issued five Guidance Documents to help companies comply with the new nutrition labeling rules
  - Guidance on evidence needed to support a citizen petition regarding the possible health effects of fiber
  - Guidance on labeling of honey and honey products
  - Draft Guidance on declaration of added sugars on honey, maple syrup, and certain cranberry products
  - Guidance on Reference Amounts Customarily Consumed (RACCs)
  - Guidance on serving sizes for foods that can reasonably be consumed in one eating occasion and dual-column labeling

- The Agency also published additional resources for companies
  - Q&A for Industry on Fiber
  - Web page on Industry Resources on the Changes to the Nutrition Facts Label

GRAS Guidance

- In November 2017, the FDA issued a Guidance document concerning substances intended for use in human or animal food that are purported to be Generally Recognized as Safe (GRAS)

- The agency also issued a Guidance Document describing best practices for convening a GRAS panel



Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry

Additional copies are available from:
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-1200
http://www.fda.gov/FoodGuidances
and
Division of Animal Foods (HFV-220)
Office of Surveillance and Compliance
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855
(Tel) 240-402-7017
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm054483.htm

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number (FDA-2016-D-4061) and with the title of the guidance document.

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

November 2017

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FSMA Implementation

- Effective Dates for Major Rules Are Fast Approaching (or Past):
  - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
    - Very Small Businesses: September 17, 2018
    - Small Businesses: September 18, 2017
    - Other Businesses: September 19, 2016
  - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
    - Very Small Businesses: September 17, 2018
    - Small Businesses: September 18, 2017
    - Other Businesses: September 19, 2016
  - Foreign Supplier Verification Programs (FSVPs) for Importers of Food for Humans and Animals
    - Compliance dates vary; see FDA FSMA website for specifics

FSMA Implementation (cont'd)

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Compliance dates vary; see FDA FSMA website for specifics
- Mitigation Strategies to Protect Food Against Intentional Adulteration
  - Very Small Businesses: July 26, 2021
  - Small Businesses: July 27, 2020
  - Other Businesses: July 26, 2019
- Sanitary Transportation of Human and Animal Food
  - Small Businesses: April 6, 2018
  - Other Businesses: April 6, 2017

FSMA Implementation (cont'd)

- Foreign Supplier Verification Program (FSVP) Requirements for Dietary Supplements:
  - Obligations apply to the *importer*
    - The U.S. owner or consignee of an article of food that is being offered for import into the United States; NOT typically the broker
  - Dietary supplements are subject to lesser FSVP requirements, but <u>there are still some applicable requirements</u>
    - Extent of requirements depends on category into which you fall:
      1. Companies required to establish specifications under the dietary supplement good manufacturing practice (GMP) regulations with respect to a dietary supplement or dietary supplement component they import for further manufacturing, processing, or packaging as a dietary supplement
      2. Companies whose *customers* are required to establish specifications under the dietary supplement GMPs with respect to a dietary supplement or dietary supplement component they import for further manufacturing, processing, or packaging as a dietary supplement
      3. All other companies importing dietary supplements

Homeopathic Drugs

1. FDA Published *Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry,* outlining the Agency's new risk-based enforcement policy
   - Published December 18, 2017

2. Categorizes homeopathic drugs as unapproved new drugs subject to the Agency's enforcement discretion

3. Withdrew previous Compliance Policy Guide (CPG) 400.000, *Conditions Under Which Homeopathic Drugs May Be Marketed*

4. Deadline for comments: March 20, 2018

Homeopathic Drugs (cont'd)

- FDA's enforcement is intended to focus on the following kinds of products:
  - products with reported safety concerns;
  - products that contain or claim to contain ingredients associated with potentially significant safety concerns;
  - products for routes of administration other than oral and topical;
  - products intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions;
  - products for vulnerable populations; and
  - products that do not meet standards of quality, strength, or purity as required under the law.

- Effective immediately

Homeopathic Drugs (cont'd)

- Follows on the footsteps of the FTC's announcement in November 2016 of a new *Enforcement Policy Statement on Marketing Claims for Over-the-Counter (OTC) Homeopathic Drugs*
  - The FTC will hold efficacy and safety claims for OTC homeopathic drugs to the same standard as other products making similar claims
  - Because homeopathic efficacy is based solely on traditional theories and there are no valid studies using current scientific methods to show a product's efficacy, the marketing of these products is likely misleading
  - FTC requires the following disclaimer on homeopathic products:
    1. *There is no scientific evidence that the product works*
    2. *The product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts*

Kratom

- In November, FDA issued a public health advisory about deadly risks associated with kratom, a botanical substance
  - Commissioner Gottlieb stated there was "clear data" on the botanical's potential for harm, pointing to reports of 36 deaths associated with kratom-containing products and a tenfold increase in calls involving kratom to U.S. poison control centers from 2010 to 2015
  - In a speech on the issue, Commissioner Gottlieb said the FDA would use import alerts and other authorities to increase seizures of kratom coming into the U.S.

Kratom (cont'd)

- On February 6, 2018, FDA announced through a statement from the Commissioner that the Agency considers kratom to be an opioid

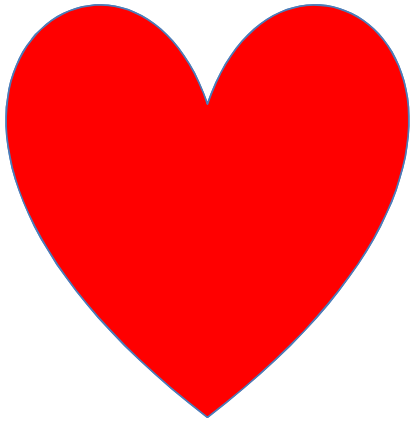
- Later that month, FDA announced the voluntary destruction and recall of a large volume of kratom supplements
  - In the press announcement, FDA encouraged all companies currently involved in the sale of kratom products to take similar steps to take their products off the market

Cannabidiol (CBD)

- In October-November 2017, the FDA issued another round of Warning Letters to four companies selling CBD products (both foods and dietary supplements)
  - Previous rounds in 2015 and 2016
- The 2017 Warning Letters objected to claims being made for the products (including in testimonials)
- BUT… the letters AGAIN stated that the FDA does not consider CBD to be a dietary ingredient (i.e., it is not permitted to be included in dietary supplement products)
  - It was authorized for investigation as a drug, was studied in drug clinical trials, and the existence of the trials is public
  - This same reasoning applies to conventional foods

Soy Protein Heart Health Claim

- On October 31, 2017, the FDA announced a proposal to revoke the regulation authorizing the use of a health claim characterizing the relationship between soy protein and coronary heart disease
  - The health claim was previously authorized in 1999
  - In 2007, the Agency announced its intention to reevaluate the scientific evidence for the claim and provided an opportunity for public comment



Soy Protein Heart Health Claim (cont'd)

- FDA's determination about whether to authorize a health claim hinges on whether there is "significant scientific agreement" (SSA) among qualified experts that publicly available scientific evidence supports the relationship between the substance and the disease

- If the proposed rule is finalized, the Agency may still permit the use of a qualified health claim

"Qualified Health Claim" for Early Introduction of Peanuts

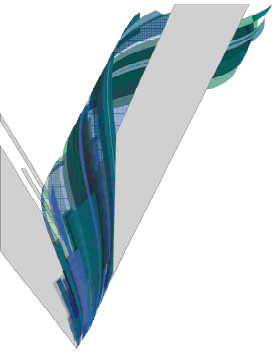
- FDA announced in September 2017 that it "acknowledges" and will "exercise enforcement discretion" regarding a qualified health claim linking the early introduction of peanuts into the diets of young children with severe eczema or egg allergies as a means to reduce their risk of peanut allergy

- Here's the claim which FDA says manufacturers can use right away:

  For most infants with severe eczema and/or egg allergy who are already eating solid foods, introducing foods containing ground peanuts between 4 and 10 months of age and continuing consumption may reduce the risk of developing peanut allergy by 5 years of age. FDA has determined, however, that the evidence supporting this claim is limited to one study. ***If your infant has severe eczema and/or egg allergy, check with your infant's healthcare provider before feeding foods containing ground peanuts.***

Vitamin D Tests

- On November, 6, 2017, FDA announced a series of actions to speed the time to market for *in vitro* vitamin D tests
- FDA published a final order classifying total 25-hydroxyvitamin D mass spectrometry systems into class II (special controls)
- FDA published a notice *proposing* to exempt total 25-hydroxyvitamin D mass spectrometry systems from 510(k) premarket notification
  - If the rule is finalized, a manufacturer of a total 25-hydroxyvitamin D mass spectrometry system will not be required to submit a 510(k) premarket notification if the device meets the general limitations of the exemption



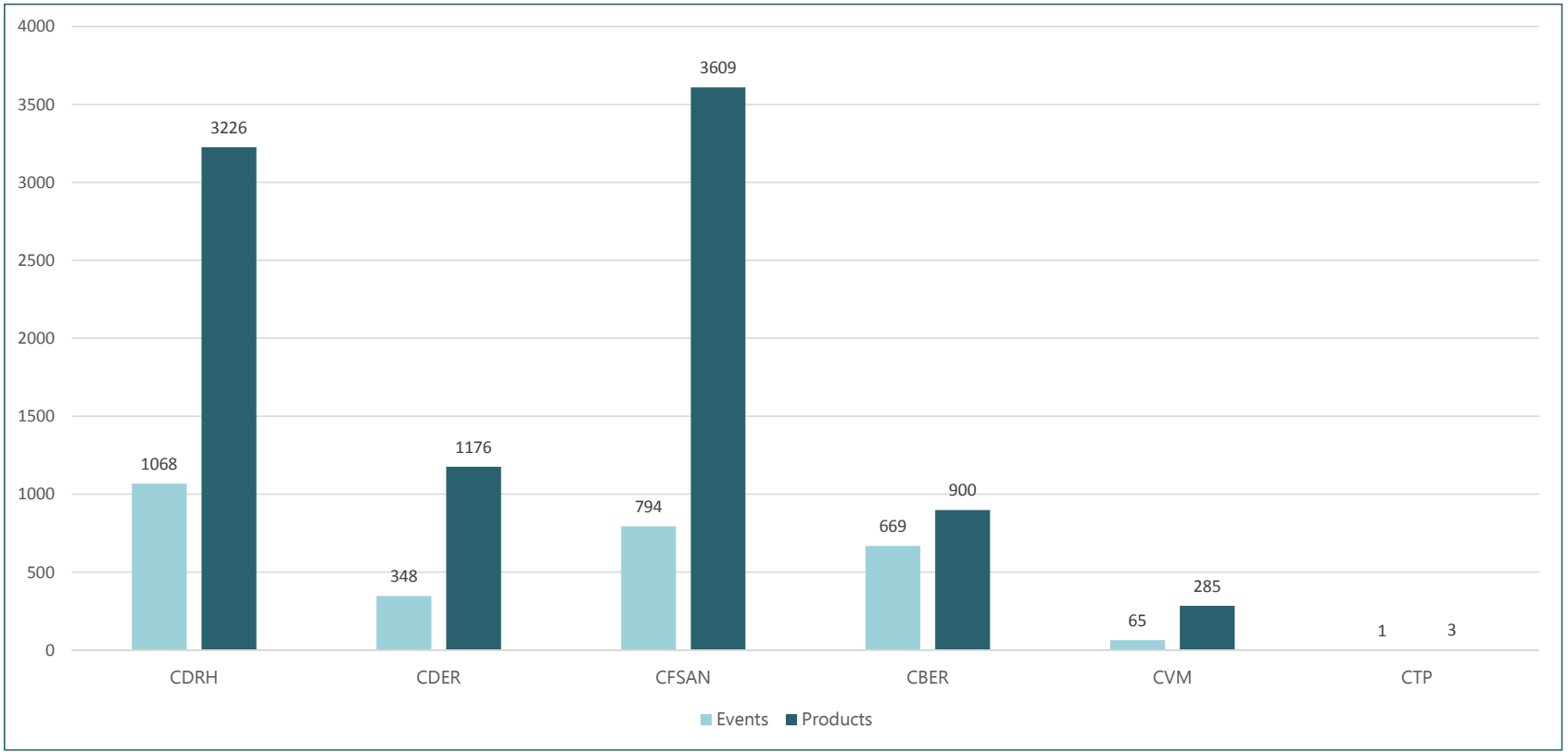
THE FOOD AND DRUG ADMINISTRATION: ENFORCEMENT TRENDS

FDA Enforcement Trends

FY 2017 Enforcement Statistics

Enforcement Type	Count
Seizures	3
Injunctions	12
Warning Letters	15,318
Recall Events	2,945
Recalled Products	9,199
Drug Product Debarments	5
Food Importation Debarments	0

FY 2017 Recalls by FDA Center—All Classes



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Highlights of Recent FDA Inspections: Form 483 Observations

- Most frequently observed violations for **food** products during facility inspections include:
  - 21 CFR 110.35(c) Lack of effective pest exclusion **(330)**
  - 21 CFR 110.20(b)(7) Screening; failure to provide adequate screening or other protection against pests **(211)**
  - 21 CFR 110.20(b)(4) Floors, walls, and ceilings; plant not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean **(192)**
  - 21 CFR 110.35(a) Buildings/sanitary; failure to maintain facilities in sanitary condition **(176)**
  - 21 CFR 110.35(a) Cleaning and sanitizing operations; failure to clean and sanitize utensils and equipment **(157)**
  - 21 CFR 110.80(b)(2) Manufacturing conditions; failure to manufacture foods under condititions that minimize contamination **(156)**

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

- Most frequently observed violations for **dietary supplement** products during facility inspections include:
  - 21 CFR 111.70(e) Lack of specifications for identity, purity, strength, and composition **(92)**
  - 21 CFR 111.103 Lack of/failure to follow written procedures for quality control **(73)**
  - 21 CFR 111.553 Lack of/failure to follow written procedures to review and investigate product complaint **(63)**
  - 21 CFR 111.75(c) Failure to verify finished batch meets product specifications for identity, purity, strength, and composition **(61)**
  - 21 CFR 111.205(a) Failure to prepare written master manufacturing record for each batch **(50)**
  - 21 CFR 111.75(a)(2)(ii)(A) Failure to qualify a supplier of a component by establishing reliablility of supplier's certificate of analysis through testing or examinations **(50)**

FDA Warning Letter Trends

- Nearly 30% of FDA Warning Letters in 2017 were issued for food or dietary supplement products
  - 19% concerned alleged GMP violations
  - 10% concerned claims
  - A third of all Warning Letters for food or dietary supplement products were to fish suppliers alone

- In 2017, eleven Warning Letters were issued to companies marketing cosmetic products allegedly making drug claims

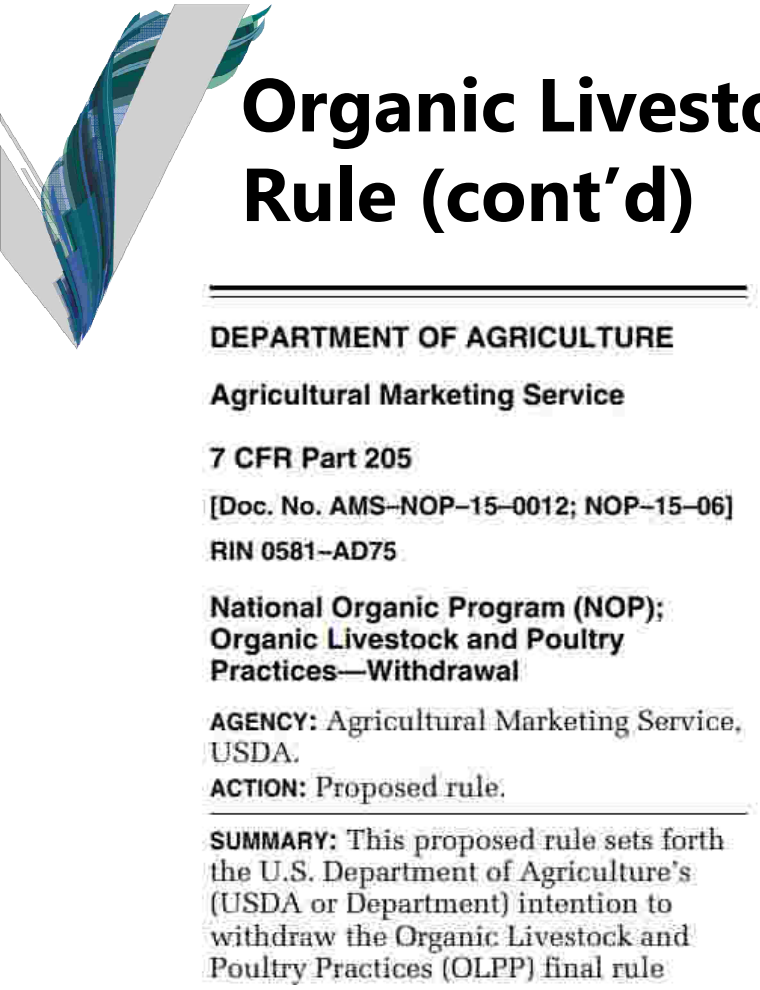
U.S. DEPARTMENT OF AGRICULTURE: RECENT DEVELOPMENTS

Organic Livestock and Poultry Practices (OLPP) Rule

- Obama Administration
  - April 13, 2016: Proposed Rule published
  - January 19, 2017: Final Rule published (scheduled to take effect March 20, 2017)

- Trump Administration
  - Delays:
    - February 9, 2017: First extension of effective date until May 9, 2017
    - May 10, 2017: Second extension of effective date until November 14, 2017
    - November 14, 2017: Third extension of effective date until May 14, 2018

Organic Livestock and Poultry Practices (OLPP) Rule (cont'd)



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS–NOP–15–0012; NOP–15–06]

RIN 0581–AD75

National Organic Program (NOP); Organic Livestock and Poultry Practices—Withdrawal

AGENCY: Agricultural Marketing Service, USDA.

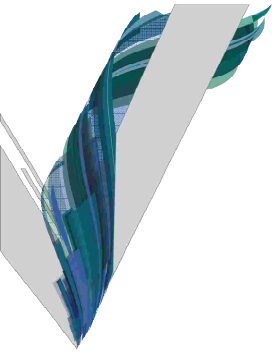
ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the U.S. Department of Agriculture's (USDA or Department) intention to withdraw the Organic Livestock and Poultry Practices (OLPP) final rule

- Notice of withdrawal: December 18, 2017
- Rationale for withdrawal: AMS takes the position that the agency does not have authority under the law to dictate animal raising/welfare standards, and the position that all regulations regarding the "care of" organic animals must be related to healthcare concerns.

Coming Soon (?): USDA GMO Disclosure and Labeling Rules

- National Bioengineered Food Disclosure Law (signed July 29, 2016)
- Public input period closed August 25, 2017 (over 112,000 responses)
- Deadline for Rules: July 29, 2018
- Process Delays:
  - Center for Food Safety sued USDA for failing to publish feasibility study by the July 2017 deadline required by the law.
  - USDA has until July to publish regulations (but they have yet to issue a Proposed Rule).
  - According to USDA AMS Website: "USDA has established a working group to develop a timeline for rulemaking and to ensure an open and transparent process for effectively establishing this new program, which will increase consumer confidence and understanding of the foods they buy, and avoid uncertainty for food companies and farmers."
  - Further delays = likely additional lawsuits.



THE FEDERAL TRADE COMMISSION: ENFORCEMENT TRENDS

Overview of FTC Authority

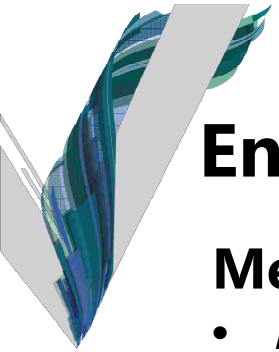
- The FTC has authority over advertising for dietary supplements, food, and beverage products under the Federal Trade Commission Act
- An "advertisement" subject to FTC jurisdiction can include marketing materials in any medium—print, electronic (online), television, radio, or verbal representations 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
  - Tests, analyses, research, or studies 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

- Two Standards:
  - **Old (FTC Consent Orders)**: at least two adequate and well-controlled human clinical studies
  - **New (Bayer, POM Wonderful Litigation)**: rejection of rigid *two RCTs* requirement



Enforcement Trends: Supplement Claims

Memory and Cognitive Claims

- *Prevagen* (Jan. 2017): FTC and 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
  - The district court dismissed the case in September 2017.
- *CogniPrin* (Feb. 2017): FTC and Maine AG complaint and settlement with three marketers for claims that product reverses mental decline by 12 years and improves memory
- *Cognify* (Jan. 2018): FTC settles charges against marketer of supplement claiming to prevent "chemo fog," cancer treatment-related cognitive dysfunction
- *NeuroPlus* (Nov. 2017): FTC and Maine AG settle charges against supplement marketer claiming that product could protect brain against Alzheimer's disease and dementia, reverse memory loss, and improve memory

Enforcement Trends: Supplement Claims

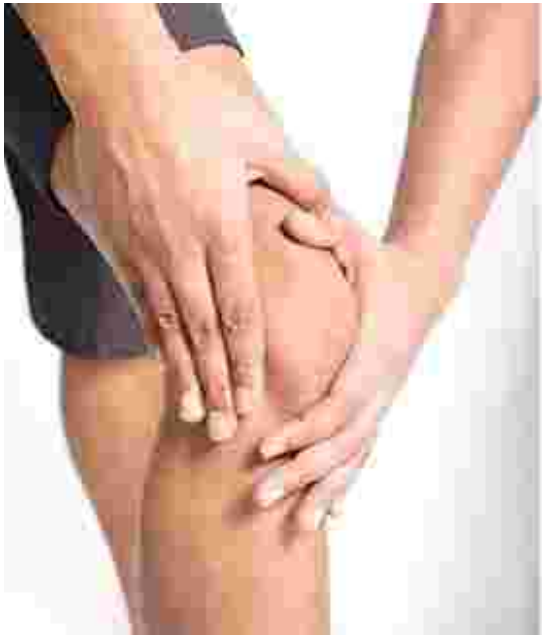
Weight Loss

- *Fastin, Lipodrene, Benzedrine, and Stimerex-ES* (Oct. 2017): FTC wins judgment finding marketer of supplements in contempt of violating previous court orders for making "rapid fat loss" and "fat burner" claims
- *NutriMost Ultimate Fat Loss System* (Apr. 2017): FTC settles case against system marketer claiming that personalized supplements could help consumers permanently lose 20 to 40 pounds in 40 days
- *Pure Green Coffee Bean Plus, RKG Extreme* (Oct. 2017): FTC mails $9.8 million in refunds to consumers misled by weight loss supplement claims

Enforcement Trends: Supplement Claims

Joint Pain

- *BioTherapex* (Nov. 2017): FTC settles charges against marketer of supplement to treat arthritis and back and joint pain
- *FlexiPrin* (Aug. 2017): FTC and Maine AG settle charges against marketer of supplement to reduce joint and back pain, inflammation, and stiffness in as little as two hours



Enforcement Trends: Advertising Practices

Influencers and Material Connection Disclosures

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Enforcement Trends: Advertising Practices

Influencers

- FTC enforcing against marketers paying social medial influencers to promote products without adequate disclosure
  - Warner Brothers settlement (2016) – marketing campaign for video game
  - CS: GO Lotto (2017) – paid gamers up to $55,000 to promote the game on social media. Contract prevented influencers from making claims that could impair the name, reputation, or goodwill of the marketer.
- FTC sent 90 "educational letters" to influencers in April 2017
- 21 influencers receive subsequent warning letters from the Agency

What Is the Big Deal? Disclosure of Material Connections

Part IV

Federal Trade Commission

16 CFR 255

Guides Concerning the Use of Endorsements and Testimonials in Advertising Federal Acquisition Regulation; Final Rule

§ 255.5 Disclosure of material connections.

When there exists a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement (*i.e.*, the connection is not reasonably expected by the audience), such connection must be fully disclosed.

When Do I Have to Disclose?

- Any "material connection" that would not be expected:
  - Payment
  - Free product
  - Other things of value
  - Other business or family relationship to seller

Where Do I Have to Disclose?

- Disclosures need to be unavoidable
  - Early and often: Placed at beginning of longer post.
  - Grabs the attention: Not in long list of hashtag disclosures. Not "below the fold" or after "read more."
  - Where viewers likely to look: if a video, then in the video

Enforcement Trends: Advertising Practices

Testimonials

- An advertisement employing endorsements will be interpreted as representing that the product or service is effective for the purpose depicted in the advertisement

Native Ads and Advertorials

- Native ads often resemble the design, style, and functionality of the media in which they are disseminated
  - Lord & Taylor (2016)

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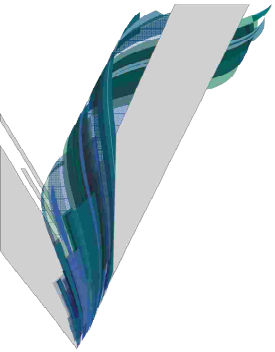
Enforcement Trends: Other Issues

Other Issues of Interest:

- **Health-Related Claims**
  - Opiate addiction
  - Solutions for serious health conditions (HIV, cancer)
- **Green Marketing**
  - "Organic"
  - "Biodegradable"
- **Consumer Privacy**
- **Negative Options and "Free Trials"**



STATE ATTORNEYS GENERAL/COUNTY DISTRICT ATTORNEYS: AUTHORITY AND ACTION

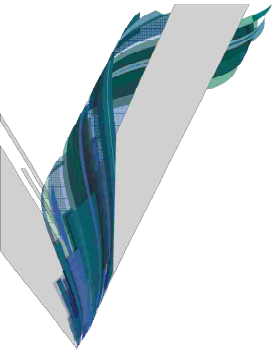
State AG: Authority

- State AG has very broad consumer protection authority
  - In California, the county district attorneys (DAs) have authority to bring cases
- Enforcement authority is derived from Unfair and Deceptive Acts and Practices (UDAP) Statutes
  - 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

State AG: Enforcement

- Focus of state AGs and county DAs recently:
  - Website disclosures of renewal terms for continuity (auto-renewal) programs
  - Alleging that claims made for dietary supplements are drug claims

- Major dietary supplement retailer settled with the Oregon AG:
  - Agreed to stop selling products if the FDA issues a Warning Letter or other written notice that a product is unsafe or unlawful



CALIFORNIA'S PROPOSITION 65

Prop. 65: Overview

- Proposition 65 requires businesses to provide "*clear and reasonable*" warning before knowingly and intentionally exposing anyone to a chemical known to the state to cause cancer, birth defects, or other reproductive harm
- List now includes approximately **900** chemicals
- Exemptions from requirements:
  - Businesses with fewer than 10 employees
  - Showing no significant risk of exposure
  - Amount of chemical under established "safe harbor"

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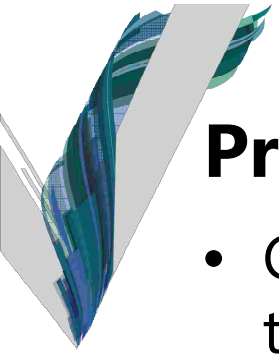


Prop. 65: Enforcement

- Compliance with Proposition 65 can be enforced by the state or by private plaintiffs
  - Most enforcement by private plaintiffs monetary settlements and injunction
- 2016: 760 total settlements. $30,150,111 in settlement payments
- Dietary supplements common targets of Proposition 65 notices of violation
  - Approximately **70 Notices** filed against supplement marketers in 2017

Prop. 65: Enforcement (cont'd)

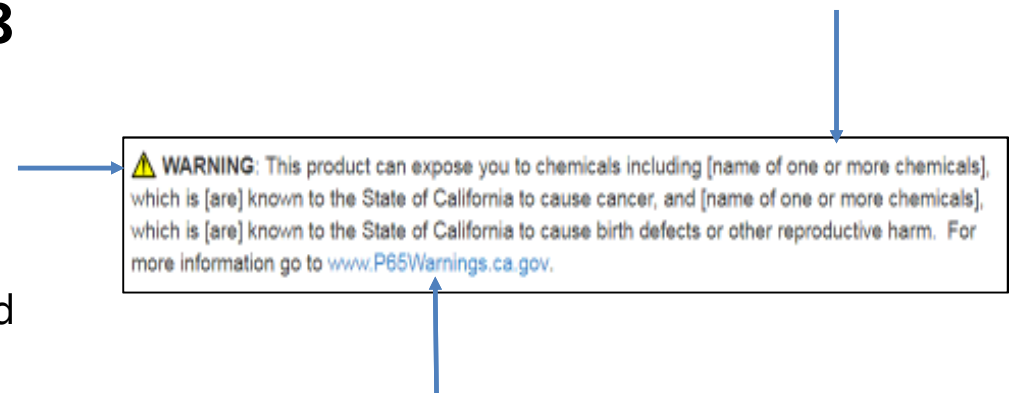
- Commonly noticed chemicals:
  - Dietary Supplements: Lead and lead compounds, mercury
  - Foods: Acrylamide, furfuryl alcohol
  - Cosmetics: Cocamide DEA, benzophenone, titanium dioxide (cases dismissed)

- Court decision last week concerning glyphosate (RoundUp)
  - Glyphosate listing based on an International Agency for Research on Cancer (IARC) finding that it is "probably" carcinogenic to humans
  - Federal district judge ruled to stop CA from requiring cancer warning on products containing the pesticide
  - Opinion: "Almost all other regulators have concluded that there is insufficient evidence that it causes cancer"

- Coming soon: Processed meat and red meat? Both listed by IARC

Prop. 65 New Warning Requirements

- Effective on **August 30, 2018**
- Major Changes:
  - **Warning content**:
    - Identification of chemicals
    - Prop 65 URL
    - Designated symbol (not required for foods or supplements)



  - **Online warning prior to checkout**
    - Placed on product display page;
    - Given via hyperlink using "WARNING"; or
    - Prior to payment (e.g., pop-up when placing item in virtual shopping cart)
  - **Short form warning option**
    - (e.g., "Warning: Cancer and Reproductive Harm")
    - Must be in at least 6-point font

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