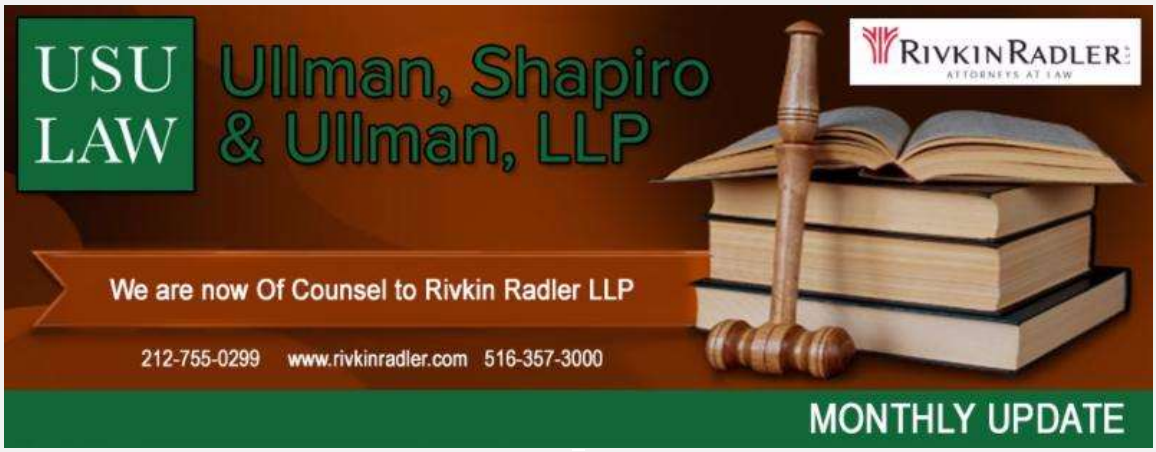

1. Rivkin Partner Geoffrey R. Kaiser will be a presenter at the ACI 4th Annual Legal, Regulatory and Compliance Forum on Dietary Supplements held in Conjunction with the Council for Responsible Nutrition

At the conference, which will be held in New York City June 27-28, Jeff will be on a panel with FDA counsel discussing, "Understanding New Government Enforcement Priorities in the Aftermath of USP Labs and What it Means for the Dietary Supplement Industry."

For more information:
http://www.crnusa.org/ACI/P10-669-CRN16.pdf

2. FDA Issues FINAL regulations for Nutrition Facts and Supplement Facts -- All Conventional Foods and Many Dietary Supplements will be affected

- An updated design to highlight "calories" and "servings.
- Amendments for serving sizes that more closely reflect the amounts of food that people currently eat.
- Declaration of grams and a % Daily Value for "added sugars".
- "Dual column" labels to indicate both "per serving" and "per package" calorie and nutrition information for certain multi-serving food products that could be consumed in one sitting or multiple sittings. Examples include a pint of ice cream and a 3-ounce bag of chips.
- For packages that are between one and two servings, such as a 20 ounce soda, the calories and other nutrients will be required to be labeled as one serving because people typically consume it in one sitting.
- Updated Daily Values for some nutrients like sodium, dietary fiber and vitamin D.
- Declaration of Vitamin D and potassium that will include the actual gram amount, in addition to the %DV. %DV for calcium and iron will continue to be required, along with the actual gram amount. Vitamins A and C will no longer be required because deficiencies of these vitamins are rare, but these nutrients can be included on a voluntary basis.
- "Calories from Fat" will be removed because research shows the type of fat is more important than the amount. "Total Fat," "Saturated Fat," and "Trans Fat" will continue to be required.

- An abbreviated footnote to better explain the %DV.

The FDA is also making minor changes to the Supplement Facts label found on dietary supplements to make it consistent with the Nutrition Facts label (primarily concerning macronutrients and vitamins and minerals for consistency with Nutrition Facts).

Effective Date compliance information, provided by FDA, is below.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm502182.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Nutrition Facts and Supplements Facts Regulation - https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-11867.pdf

Serving Size regulation -- https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-11865.pdf

Highlights of the changes --
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#images

At a Glance: Highlights of the Final Nutrition Facts Label --
http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM502305.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

We have obtained the following explanatory information from FDA concerning the effective date -

Dear Mr. Shapiro,

Products that are labeled in production on or after July 26, 2018 (and July 26, 2019 for manufacturers with less than $10 million in annual food sales) must affix a nutrition label that meets FDA's new nutrition labeling requirements in 21 CFR 101.9 and 21 CFR 101.36. Products that were labeled in production before July 26, 2018 (and July 26, 2019 for manufacturers with less than $10 million in annual food sales) may continue to be shipped in interstate commerce, which includes being able to be shipped from a warehouse. These products may also remain on store and warehouse shelves.

FDA does not object to the use of a sticker for providing a revised nutrition label that meets our new requirements in 21 CFR 101.9 and 21 CFR 101.36 before new packaging is printed. The sticker label should not cover any other mandatory information and should adhere to the package during normal handling.

Please let us know if you have other questions.

Nutrition Programs Staff
Office of Nutrition, Labeling, and Dietary Supplements
FDA, Center for Food Safety and Applied Nutrition

3. A toxic combo of bad regulations, lawyers -- May 20, 2016

An editorial from a major California newspaper piece on Prop 65. This is a bad law.

http://www.ocregister.com/articles/bpa-716490-lawyers-health.html

4. From NPA -- Opponents in U.S. Senate are Planning an Attack on the Dietary Supplement Industry

NPA learned that Senator Richard Blumenthal (D-Connecticut) planned to offer an amendment to the Fiscal Year 2017 (FY17) National Defense Authorization Act (NDAA) that sought to impose burdensome and expensive regulations while restricting soldiers' access to the supplements they rely on to stay healthy and in fighting shape.

Specifically, the Blumenthal amendment would require dietary supplements sold by a commissary store, exchange store, or other retail establishment operating on a military installation be verified by an independent third-party for recognized public standards of identity, purity, strength, and composition, and adherence to related process standards.

NPA's talking points in response to the amendment are as follows:

The dietary supplement cGMPs (21 CFR Part 111) have been in place since 2008 with FDA performing nearly 700 inspections of domestic firms annually. Inspections can result in documented deficiencies for a firm, which can lead to legal consequences (injunction, seizures) if not corrected within 15 days. FDA has aggressively pursued enforcement actions above warning letters for any firm failing to be in compliance with federal laws. The military can view all active 483 inspection results and warning letters sent by FDA at www.fda.gov

The Armed Services can already require that a supplement is in compliance with Defense Commissary Agency policy on inventory carried by commissaries.

3rd party verification/certification for dietary supplement cGMPs are not mandatory at present and while they may have some utility for customer confidence, requiring them on military installations will only increase prices to soldiers and limit access to products that are already compliant with federal laws for public health and safety. FDA does not recognize any 3rd party auditing bodies for dietary supplement compliance.

Many soldiers get supplements from family members sending them in the mail. Are we going to require these be 3rd party verified as well?

This is the same tactic Sen. Blumenthal took during last year's consideration of the NDAA. He was resoundingly defeated.

During the Senate Armed Services Committee mark-up of the FY17 NDAA, Sen. Blumenthal withdrew his amendment from consideration in order to push for its passage when the NDAA comes to the Senate floor for a vote.

NPA will continue to oppose the Blumenthal amendment - and any other amendments - that would impose redundant and invasive regulations which will negatively impact those who protect and defend our liberty on a daily basis. They fight for our freedoms, and we need to fight for

theirs.

Tell your U.S. Senators to do the same -- http://cqrcengage.com/npa/app/write-a-letter?0&engagementId=167613

Trade Association joint letter -- http://www.npainfo.org/App_Themes/NPA/docs/press/PressReleases/FINAL_JointDSTA_BlumenthalAmdt_NDAA_052316.pdf

5. NPA Works to Repeal Puerto Rico Rule that Raises Prices, Limits Access to Nutritional Supplements February Administrative Order by Puerto Rico Health Secretary Creates New Requirements That Go Above and Beyond Existing Federal Requirements Without Any Benefit; Hurts Consumers and Small Business

On February 9, 2016, the Puerto Rican Secretary of Health issued Administrative Order #346 without any notice and comment period which includes a host of costly and onerous requirements:

The Order imposed a regulatory scheme in Puerto Rico for all distributors of dietary Supplements in Puerto Rico. It requires a burdensome product-by-product registration per store requiring $25 fee for every variation of a supplement by size, color, SKU.
All Manufacturers must likewise file an application and pay an additional $500 fee. Distributors must also register and pay an additional $100 fee. NPA is encouraging members to visit its grassroots website and reach out to Congress and tell them to stop Puerto Rico from creating an arbitrary tax on the industry as the relief package is debated.
Thank you to NPA for this information.

NPA Press Release:
http://www.npainfo.org/App_Themes/NPA/docs/press/PressReleases/Puerto%20Rico%20Release.pdf

Puerto Rico Administrative Order
346: http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/Talking%20Points%20on%20Puerto%20Rico%20Administrative%20Order%20346.pdf

http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/PR%20Admin%20Order%20346.pdf

6. Study Showing Dietary Supplements Can Make Chemotherapy Less Effective Spurs McCaskill Inquiry --Senator asks medical associations what guidance is being offered to doctors

Senator Claire McCaskill sends letters question about the safety of taking dietary supplements while undergoing treatment for cancer.

https://www.mccaskill.senate.gov/media-center/news-releases/study-showing-dietary-supplements-can-make-chemotherapy-less-effective-spurs-mccaskill-inquiry-

7. New York Class Action -- Kimlan Foods sued over "No Preservatives" Claim

As stated in the complaint (Kimlan Complaint):

Defendants' "No Preservatives Added" Claim is deceptive. Defendants engaged in deceptive labeling practices by failing to disclose that the Products contain Citric Acid as a preservative and/or by expressly representing on the front label that the Products contain "No Preservatives." All of the Products contain citric acid, which is commonly used as a preservative in commercial food and beverage products. Fresh, high quality produce, as claimed to be used by Defendants, is fertile ground for bacterial/mold growth. Without the addition of preservatives, a jar of fresh produce would certainly not keep for weeks as intended.
The FDA regulations require that any ingredient in a food or dietary supplement intended to act as a preservative must be identified as such: "bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

8. LA Superior Court approves preliminary "natural claim" settlement in Flax Beverage case.

As many courts are putting "natural claim" class action lawsuits on ice as the FDA probes what the term "natural" means, some companies are settling to avoid the expense and uncertainty of litigation.

http://www.foodnavigator-usa.com/Regulation/LA-Superior-Court-approves-preliminary-natural-claim-settlement

9. New York Class Action - Colgate sued for false/ exaggerated tooth whitening claims

As stated in the Complaint (Colgate Complaint):

Since October 2013, Colgate has falsely represented that Colgate Optic White toothpaste "Goes Beyond Surface Stain Removal to Deeply Whiten" teeth. Since February 2014, Colgate has falsely represented that Colgate Optic White Platinum toothpaste "Deeply Whitens More Than 3 Shades." Both products contain the same supposed whitening ingredient, 1% hydrogen peroxide. But the 1% hydrogen peroxide in Optic White does not go beyond surface stain removal, and does not deeply whiten teeth because there is not enough hydrogen peroxide in toothpaste, and the peroxide is not in contact with teeth for long enough.
It is alleged that plaintiff and members of the Class purchased Colgate Optic White and have been injured in fact because Optic White was not effective for deep whitening or whitening intrinsic stains.
No doubt part of the issue is that this particular toothpaste was sold as a premium product and at a premium price.
The attached complaint discusses in detail purported problems with toothpaste whitening claims.

10. FDA Must Ban Sales of Highly Concentrated Caffeine Products

These efforts concern "pure" bulk powder caffeine and highly concentrated liquid caffeine product, not typical energy drinks and unit dose dietary supplements.

On Tuesday at the U.S. Capitol Building, the nonprofit Center for Science in the Public Interest (CSPI) joined Sens. Dick Durbin of Illinois, Richard Blumenthal of Connecticut and Sherrod Brown of Ohio in calling for the ban. Families whose loved ones have died after taking bulk

powdered caffeine also joined the press conference.

http://www.naturalproductsinsider.com/blogs/insider-law/2016/04/sens-durbin-brown-call-on-fda-again-to-ban-bulk-p.aspx

CSPI on Bulk Caffeine -- http://www.cspinet.org/new/201604261.html

11. Lawsuit Targets Cheez-It "Whole Grain" Crackers, Which are Mostly Made of Refined White Flour

As stated by CSPI:

A 30-gram serving of Whole Grain Cheez-Its contains only one gram of dietary fiber, while the Original Cheez-It has "less than one gram." The words "WHOLE GRAIN," or in some cases, "MADE WITH WHOLE GRAIN" appear prominently on five of the six package panels, including the front of the box, known as the principal display panel. In small print on the front of the box, Kellogg states that the product has just 5 grams of whole grain per serving; some boxes state that the product has 8 grams. The Dietary Guidelines for Americans recommends that at least half of the grains people eat be whole grains. Less than half the grains in both versions of Whole Grain Cheez-Its are whole.
Apparently, despite the "whole grain" claims, the majority of the grain used in these products is not whole grain.

Complaint: http://cspinet.org/new/pdf/cheeze-its-complaint-5-19-16.pdf

Press release: http://www.cspinet.org/new/201605191.html

12. NAD

NAD Recommends Prestige Discontinue Claim for Monistat 'Stay Fresh' Following Challenge by Church & Dwight
http://www.asrcreviews.org/nad-recommends-prestige-discontinue-claim-for-monistat-stay-fresh-following-challenge-by-church-dwight/

In Response to NAD Inquiry, Maker of 'Anti-Aging' Gin Says Product has Been Discontinued
http://www.asrcreviews.org/in-response-to-nad-inquiry-maker-of-anti-aging-gin-says-product-has-been-discontinued/

Native Advertising: NAD Reviews Joyus' Product Videos at Magazine's Online Edition, Recommends Modifications
http://www.asrcreviews.org/native-advertising-nad-reviews-joyus-product-videos-at-magazines-online-edition-recommends-modifications/

Beiersdorf Says it Will Discontinue Six-Hour Claim for 'Aquaphor' Diaper Rash Cream Following NAD Inquiry
http://www.asrcreviews.org/beiersdorf-says-it-will-discontinue-six-hour-claim-for-aquaphor-diaper-rash-cream-following-nad-inquiry/

NAD Recommends Intraceuticals Discontinue Challenged Claims for 'Atoxelene' Products
http://www.asrcreviews.org/nad-recommends-intraceuticals-discontinue-challenged-claims-for-

atoxelene-products/

Green Tea Dietary Supplement -- NAD Recommends Mega-T Discontinue 'Burns Fat' Claim; Company Voluntarily Discontinues Certain Other Claims Challenged by CRN
http://www.asrcreviews.org/nad-recommends-mega-t-discontinue-burns-fat-claim-company-voluntarily-discontinues-certain-other-claims-challenged-by-crn/

NAD Recommends Clorox Modify Packaging to Clarify Role of Zinc Pyrithione in its 'Glad Tall Kitchen Drawstring Bags'
http://www.asrcreviews.org/nad-recommends-clorox-modify-packaging-to-clarify-role-of-zinc-pyrithione-in-its-glad-tall-kitchen-drawstring-bags

NAD Recommends Genomma Modify Current Broadcast Ad for 'Silka' to Avoid Certain Comparisons to Other OTC Athlete's Foot Products
http://www.asrcreviews.org/nad-recommends-genomma-modify-current-broadcast-ad-for-silka-to-avoid-certain-comparisons-to-other-otc-athletes-foot-products/

NAD Recommends SharkNinja Discontinue Certain Claims Challenged by Dyson, Including '2-to-1' Preference Claim
http://www.asrcreviews.org/nad-recommends-sharkninja-discontinue-certain-claims-challenged-by-dyson-including-2-to-1-preference-claim/

13. USDA - NOP -- Fact Sheet on Use of the USDA Organic Seal

The National Organic Program (NOP) has posted a new fact sheet to its website. The document explains allowed uses for the USDA organic seal in media and on materials not intended for marketing organic products. It also provides examples of previously approved uses. Access the fact sheet - Using the USDA Organic Seal: Media, Marketing & Educational Materials.

Find this and other fact sheets regarding organic regulations, certification, practices and more online at
https://www.ams.usda.gov/publications/Fact_Sheets?field_term_program_tid=218&=Filter

14. FTC

Marketers of Dietary Supplement Amberen Settle FTC Charges Regarding Misleading Weight-Loss and Menopause Relief Claims

Lunada Biomedical, Inc. and its three principals have settled Federal Trade Commission charges that they deceptively marketed Amberen, a dietary supplement, to women over 40 who are perimenopausal or menopausal, making a range of unsupported claims about its ability to help users lose weight and belly fat, and relieve menopause-related symptoms such as hot flashes and night sweats.

This appears to have been the dietary ingredients -- Ammonium Succinate, Calcium disuccinate, Magnesium disuccinate, Zinc difumarate, Glycine, Tocopheryl acetate, and Monosodium L-glutamate.

The proposed order includes an injunction from making various claims "unless they have human clinical testing that meets certain requirements and is sufficient to substantiate that the claims are

true", "failing to disclose any material connections (such as financial relationships) they have with endorsers." And subjects the defendants to a $40 million judgment, all but $250,000 of which will be suspended based on their inability to pay.

https://www.ftc.gov/news-events/press-releases/2016/05/marketers-dietary-supplement-amberen-settle-ftc-charges-regarding

FTC Approves Final Lord & Taylor Order Prohibiting Deceptive Advertising Techniques

According to the FTC's complaint, issued against the company in March 2016, Lord & Taylor deceived consumers by placing a seemingly objective "news" article in the online publication *Nylon* and creating a
Nylon Instagram post, without disclosing that the placements actually were paid native advertisements for the company's 2015 new Design Lab clothing collection.
The Commission's complaint also charged that as part of the Design Lab rollout, the company paid 50 online fashion "influencers" to post Instagram pictures of themselves wearing a paisley dress from the new collection, but failed to disclose they had given each influencer the dress, as well as thousands of dollars, in exchange for their endorsement.
The consent order prohibits Lord & Taylor from misrepresenting that paid ads are from an independent source or that an endorser is an independent or ordinary consumer. In addition, the company must ensure that its endorsers clearly disclose when they have been compensated in exchange for their endorsements.
https://www.ftc.gov/news-events/press-releases/2016/05/ftc-approves-final-lord-taylor-order-prohibiting-deceptive?utm_source=govdelivery

Marketers of "Mosquito Shield Bands" to Pay $300,000, Barred from Making Misleading Pest-Control Claims under Settlement with FTC

Viatek Consumer Products Group, Inc. and company owner and President Lou Lentine have agreed to settle Federal Trade Commission charges that they made deceptive claims for Viatek-brand Mosquito Shield Bands. The Commission also charged Lentine and Viatek with violating a 2003 administrative order prohibiting Lentine from making product claims without competent and reliable evidence to back them up.

* * *

According to the FTC's February 2015 complaint, Lentine and Viatek marketed Mosquito Shield Bands, wristbands containing mint oil, directly to consumers and through retailers, including the home shopping channel HSN and claimed the wristbands would protect users from being bitten by mosquitos.

* * *

The proposed order settling the FTC's charges requires the defendants to have competent and reliable scientific evidence for future claims about the benefits, performance, or efficacy of any pest control product, and to have appropriate substantiation for similar claims made about any product they sell. It also prohibits the defendants from violating the 2003 FTC order and requires them to pay $300,000 to the Commission.
https://www.ftc.gov/news-events/press-releases/2016/05/marketers-mosquito-shield-bands-pay-300000-barred-making?utm_source=govdelivery

FTC Issues Warning Letters Regarding Agency's Eyeglass Rule -- Prescribers Must Provide Patients with Eye Glass Prescriptions

FTC staff sent 38 letters to eyeglass prescribers warning them of potential violations of the agency's Ophthalmic Practice Rules, known as the Eyeglass Rule, which ensures consumers the right to comparison shop for prescription eyeglasses.

The Rule requires prescribers to provide patients with a copy of their eyeglass prescription immediately after an eye exam, even if the patient does not request it. Under the Rule, prescribers cannot require that patients buy eyeglasses as a condition of providing them with a copy of their prescription.

For more information: https://www.ftc.gov/news-events/press-releases/2016/05/ftc-issues-warning-letters-regarding-agencys-eyeglass-rule?utm_source=govdelivery

15. FDA

FDA Closes Comment Period on definition of "Natural" Claims for food (including dietary supplements) on May 10

Trade Association Comments:

APHA --http://ahpa.org/Portals/0/PDFs/Advocacy/AHPA_Natural_Comments_FDA.pdf

CRN -- http://www.crnusa.org/pdfs/CRN_Comments_FDA-NATURAL051016.pdf

GMA --http://www.gmaonline.org/file-manager/2016_0510_GMA_Natural_Comments.pdf

NPA -- http://www.npainfo.org/App_Themes/NPA/docs/press/PressReleases/Definition%20of%20Natural%20Comments%20-%20FINAL.pdf

News: http://www.nutraingredients-usa.com/Regulation/What-is-natural-Over-to-you-FDA

FDA Considering re-defining "Healthy" Claims -- Statement on FDA's Actions on Labeling of KIND Products -- May 10, 2016

FDA will reexamine is regulatory definition of "healthy", which was established over 20 years ago (scroll to the bottom part of the regulation:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.65). The current definition restricts claims for products that do not meet the definition of "low fat". But, current science acknowledges that there are "good" fats and that, for example, nuts can be part of a "healthy" diet.

In March 2015, the FDA issued a warning letter to KIND LLC, because the labels and labeling of KIND's products bore a variety of nutrient content claims but the products did not meet the requirements to make such claims.

The FDA issued a closeout letter to KIND on April 20, 2016 after an evaluation of the corrective actions taken by the firm in response to the 2015 warning letter. Some of KIND's corrective actions included removing and amending certain nutrient content claims on product labels and labeling, as appropriate. The FDA concluded that KIND satisfactorily addressed the violations

contained in the warning letter.

Following receipt of the closeout letter, KIND requested confirmation that it could use the phrase "healthy and tasty" only in text clearly presented as its corporate philosophy, where it isn't represented as a nutrient content claim, and does not appear on the same display panel as nutrient content claims or nutrition information. In our discussions with KIND, we understood the company's position as wanting to use "healthy and tasty" as part of its corporate philosophy, as opposed to using "healthy" in the context of a nutrient content claim. The FDA evaluates the label as a whole and has indicated that in this instance it does not object.

Consumers want to make informed food choices and it is the FDA's responsibility to help them by ensuring labels provide accurate and reliable nutrition information. In light of evolving nutrition research, forthcoming Nutrition Facts Labeling final rules, and a citizen petition, we believe now is an opportune time to reevaluate regulations concerning nutrient content claims, generally, including the term "healthy." We plan to solicit public comment on these issues in the near future.

News: http://www.wsj.com/articles/fda-seeks-to-redefine-healthy-1462872601

http://www.foodnavigator-usa.com/Regulation/FDA-tells-KIND-it-can-use-term-healthy-on-pack

FDA Issues Final Guidance on Frequently Asked Questions About Medical Foods -- May 12, 2016

FDA has updated its medical foods guidance. The final guidance "Frequently Asked Questions About Medical Foods: Second Edition," represents FDA's current thinking on medical foods. This second edition, which finalizes the August 2013 draft guidance, provides responses to additional questions about the definition and labeling of medical foods, types of diseases and conditions that a medical food could be used to manage, and updates prior responses from the previous edition of the guidance.
Medical foods are specially formulated and processed for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary food or certain nutrients, or who has other special medically determined nutrient requirements that cannot be met by modification of a normal diet alone. Medical foods are not those foods simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.

Although this is a final guidance, comments may be submitted at any time.

For Additional Information: Final Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition

FDA Releases Final Guidance Regarding the Food Labeling Term "Evaporated Cane Juice"

FDA has released a final guidance for industry rejecting the term "evaporated cane juice." FDA's view is that the term "evaporated cane juice" is false or misleading because it suggests that the sweetener is fruit or vegetable juice or is made from fruit or vegetable juice, and does not reveal that the ingredient's basic nature and characterizing properties are those of a sugar.

FDA's position is that the ingredient must be identified as "Sugar", but will permit optional parentheticals that are truthful, non-misleading descriptors to distinguish the ingredient from

other cane-based sweeteners, but may not include the word "juice".

This will surely lead to more class actions.

- Federal Register Notice: Ingredients Declared as Evaporated Cane Juice: Final Guidance for Industry
- Guidance for Industry: Ingredients Declared as Evaporated Cane Juice Ingredients Declared as Evaporated Cane Juice

FDA Issues Draft Guidance for Qualified Facilities under the FSMA Preventive Controls Rules -- May 13, 2016

FDA announced the publication of draft guidance to assist qualified facilities, such as very small businesses, in complying with the Preventive Controls for Human Food Rule or the Preventive Controls for Animal Food Rule under the FDA Food Safety Modernization Act (FSMA).

A business that meets the definition of a "qualified facility" is subject to modified requirements of the preventive controls rules. These modified requirements can be met by submitting a form to FDA, attesting to the business's status as a qualified facility and attesting that the facility is implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations.

This draft guidance, "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food) " explains how to determine whether a business meets the definition of "qualified facility" and how to submit the FDA form attesting to its status as a qualified facility. The draft guidance will be available for public comment for 180 days starting May 16, 2016. The FDA will consider all comments before completing a final version.

For more information:

- Federal Register Notice
- Draft Guidance for Industry: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)
- Draft Instructions for Submitting Your Attestation: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)
- Preventive Controls for Human Food final rule
- Preventive Controls for Animal Food final rule
- Draft Form FDA 3942a
- Draft Form FDA 3942b

FDA issues final food defense regulation -- Regulation marks the seventh and final major rule under FDA Food Safety Modernization Act

FDA finalized a new food safety rule under FSMA that will help to prevent wide-scale public health harm by requiring companies in the United States and abroad to take steps to prevent intentional adulteration of the food supply. While such acts are unlikely to occur, the new rule advances mitigation strategies to further protect the food supply.
Under the new rule, both domestic and foreign food facilities, for the first time, are required to complete and maintain a written food defense plan that assesses their potential vulnerabilities to

deliberate contamination where the intent is to cause wide-scale public health harm. Facilities now have to identify and implement mitigation strategies to address these vulnerabilities, establish food defense monitoring procedures and corrective actions, verify that the system is working, ensure that personnel assigned to these areas receive appropriate training and maintain certain records.

The FDA has now finalized all seven major rules that implement the core of FSMA. The Intentional Adulteration final rule builds on the Preventive Controls rules for human food and animal food, the Produce Safety rule, Foreign Supplier Verification Program rule, Accreditation of Third-Party Certification rule and the rule on Sanitary Transportation of Human and Animal Food. These seven rules will work together to systemically strengthen the food safety system and better protect public health.

A free webinar is planned for June 21, 2016 to present key pieces of the final rule.

For More Information

- Intentional Adulteration Final Rule Fact Sheet
- Federal Register Notice

FDA Updates Biological Analytical Manual

Microbiological Methods for Cosmetics

FDA Issues Draft Guidance to Industry for Voluntarily Reducing Sodium
FDA has issued a draft guidance for public comment that provides voluntary sodium reduction targets for the food industry. The draft short-term (2-year) targets seek to decrease sodium intake to about 3,000 mg per day. The long-term (10-year) targets seek to reduce sodium intake to 2,300 milligrams per day. The targets, which cover nearly 150 food categories, are intended to complement many existing efforts by food manufacturers, restaurants and food service operations to reduce sodium in foods.
The comment period on this draft guidance opens June 2, 2016. Although comments are accepted at any time, to ensure that the agency considers comments on this draft guidance before it begins work on the final version of the guidance, submit comments within 90 days (by August 31, 2016) on Issues 1 through 4 listed in section IV of the notice announcing the availability of the draft guidance and within 150 days (by October 31, 2016) on Issues 5 through 8 listed in section IV of this notice. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2014-D-0055, as listed in the notice of availability that publishes in the *Federal Register*.
For More Information

- Sodium Reduction At A Glance (includes Questions & Answers)
- Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods
- Federal Register Notice Announcing the Draft Guidance

- Blog: Reducing Sodium in the Food Supply

Warning Letters

Letter Issue Date	Company Name	Issuing Office	Subject	Close Out Date
November 06, 2015	Jh Seafood Supply Inc	Los Angeles District Office	Seafood HACCP/CGMP for Foods/Adulterated/Insanitary Conditions	Not Issued *
May 25, 2016	Hari Cards & Convenience, Inc.	Center for Tobacco Products	Family Smoking Prevention and Tobacco Control Act/Adulterated/Misbranded	Not Issued *
May 20, 2016	Corden Pharma Latina S.p.A.	Center for Drug Evaluation and Research	CGMP/Active Pharmaceutical Ingredient (API)/Adulterated	Not Issued *
May 19, 2016	Megafine Pharma Limited	Center for Drug Evaluation and Research	CGMP/Active Pharmaceutical Ingredient (API)/Adulterated	Not Issued *
May 19, 2016	Seedling Enterprise, LLC	Detroit District Office	Juice HACCP/CGMP for Foods/Adulterated/Insanitary Conditions	Not Issued *
May 18, 2016	Bedford Pharmacy	New England District Office	Drug/Prepared, Packed or Held Under Insanitary Conditions/Adulterated	Not Issued *
May 13, 2016	Horizon Air Industries Inc.	Seattle District Office	Interstate Conveyance Sanitation Regulations	Not Issued *
March 10, 2016	Complete Pharmacy and Medical Solutions LLC	Florida District Office	CGMP/Compounded Drugs/Misbranding	Not Issued *
May 18, 2016	khahan LLC	Center for Tobacco Products	Family Smoking Prevention and Tobacco Control Act/Section 301(tt) Violation	Not Issued *
May 16, 2016	BBT Biotech Gmbh	Center for Drug	CGMP/Active Pharmaceutical Ingredient (API)/Adulterated	Not Issue

		Evaluation and Research		d *
May 16, 2016	David Bridgewater	Cincinnati District Office	New Animal Drug/Adulterated	Not Issued *
May 16, 2016	N.A. Sales Company Inc.	San Francisco District Office	Seafood HACCP/CGMP for Foods/Adulterated/Insanitary Conditions	Not Issued *
May 16, 2016	Qiagen Sciences LLC	Baltimore District Office	CGMP/QSR/Medical Devices/Adulterated/Misbranded	Not Issued *
May 13, 2016	Rocky Fork Formulas Inc	Cincinnati District Office	CGMP/Dietary Supplement/Adulterated/Misbranded	Not Issued *
May 12, 2016	Hannibal Company Inc	Cincinnati District Office	CGMP/Food/Prepared, Packed or Held Under Insanitary Conditions/Adulterated	Not Issued *
May 12, 2016	Somnowell, Inc.	New Orleans District Office	CGMP/QSR/Medical Devices/Adulterated	Not Issued *
May 12, 2016	Tai Heng Industry Co., Ltd.	Center for Drug Evaluation and Research	CGMP/Active Pharmaceutical Ingredient (API)/Adulterated	Not Issued *
May 05, 2016	Banner Pharmacy Services, LLC	Los Angeles District Office	CGMP/Compounded Drugs/Misbranding	Not Issued *
May 05, 2016	Renovis Surgical Technologies, Inc.	Los Angeles District Office	CGMP/QSR/Medical Devices/Adulterated	Not Issued *
May 05, 2016	www.baracoatobacconist.com	Center for Tobacco Products	Family Smoking Prevention and Tobacco Control Act/Adulterated/Misbranded	Not Issued *
February 05, 2016	Beauty & Health International Inc.	Los Angeles	CGMP/Dietary Supplement/Adulterated/Misbra	Not Issue

		District Office	nded	d *
May 10, 2016	Reviva Labs Inc	New Jersey District Office	Unapproved New Drugs/Adulterated	Not Issued *
May 06, 2016	Economax LLC	New York District Office	Unapproved New Drugs/Misbranded	Not Issued *
May 05, 2016	Empire Crab Company, Inc	Philadelphia District Office	Seafood HACCP/CGMP for Foods/Adulterated/Insanitary Conditions	Not Issued *
May 03, 2016	House of Webster, Inc	Dallas District Office	Acidified Foods/Prepared Packed or Held Under Insanitary Conditions	Not Issued *
March 28, 2016	Eclipse Aesthetics LLC	Dallas District Office	Investigational Device Exemptions (IDE)/Premarket Approval Application (PMA) Adulterated	Not Issued *
April 28, 2016	East Village Farm And Grocery	Center for Tobacco Products	Family Smoking Prevention and Tobacco Control Act/Adulterated/Misbranded	Not Issued *
April 25, 2016	Lincare, Inc.	Dallas District Office	Total Parenteral Nutrition (TPN) Drug Products/Adulterated	Not Issued *
May 04, 2016	Corey Kay	Kansas City District Office	Illegal Drug Residue	Not Issued *
May 02, 2016	Summit Beverage Group, LLC	Baltimore District Office	CGMP/Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements/Adulterated	Not Issued *
April 29, 2016	PharmaLogic CSP, Inc.	Baltimore District Office	CGMP/Compounded Drugs/Misbranding	Not Issued *
April 28, 2016	Macular Health	New Orleans District Office	New Drug/Misbranded	Not Issued *

April 27, 2016	Riddhi USA Inc.	New York District Office	CGMP/Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements/Adulterated	Not Issued *
April 27, 2016	Service First Pharmacies Inc, dba Madison Drugs	New Orleans District Office	CGMP/Compounded Drugs/Misbranding	Not Issued *
April 26, 2016	S & S Foods, Inc.	Dallas District Office	Acidified Foods/Emergency Permit Control/Adulterated	Not Issued *
April 25, 2016	Faye's Texas Naturals	Dallas District Office	Acidified Foods/Emergency Permit Control/Adulterated	Not Issued *
April 21, 2016	Hartley Medical Center Pharmacy, Incorporated	Los Angeles District Office	CGMP/Compounded Drugs/Misbranding	Not Issued