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PRE-DSHEA INGREDIENT LIST MEETING SET FOR OCTOBER 3, 2017

On October 3, 2017, from 8am to 5pm FDA's Center for Food Safety & Applied Nutrition will meet at the Wiley Auditorium, 5001 Campus Drive, College Park, MD 20740 to discuss the development of a list of dietary ingredients that pre-date the Dietary Supplement Health and Education Act of 1994 (DSHEA).

DSHEA requires the manufacturer or distributor of a new dietary ingredient (NDI) or supplement that contains an NDI to submit a premarket notification to FDA. The premarket notification must be sent to FDA at least 75 days before introducing the NDI or supplement into interstate commerce.

The Natural Products Association (NPA) compiled a pre-DSHEA list that contains more than 2,000 ingredients that it believes meet the FDA standard of "independent and verifiable." NPA has been vocal that FDA delayed the sharing

of the list and urged its members to contact their Congressional representatives to speed up the process.



The American Herbal Products Association (AHPA) on the other hand took the position that the development of a list of pre-DSHEA dietary ingredients should not have been first priority. Instead, AHPA has suggested over the years that FDA approach the NDI provisions separately, rather than in a single guidance document.

Will this meeting lead to an official pre-DSHEA list accepted and used by FDA? Could this list help the industry better understand what exactly requires NDI notification? We will keep you updated after the October 3 meeting!

<http://wholefoodsmagazine.com/news/breaking-news/fda-sets-oct-3-pre-dssea-ingredients-hearing/>

RICK COLLINS TO SPEAK AT SUPPLYSIDE WEST 2017



On Tuesday, September 26, 2017 from 3:00 – 3:45 pm, Rick Collins will be presenting "Tales of the Darkside" at the sports nutrition workshop at SupplySide West, sharing insights into the legal and regulatory landscape sports nutrition companies face, from class action and Lanham Act lawsuits to federal regulatory enforcement actions and everything in between. Other workshop speakers include Dr. Doug Kalman and Hector Lopez, MD.

Immediately following, Rick Collins will lead a panel including Bruce Kneller and Tim Ziegenfuss, PhD in a discussion about the lessons the sports nutrition

industry can learn from past challenges, covering a range of issues from stimulants to prohormones to SARMs. This panel will provide an opportunity for audience participation on how the industry can avoid such challenges going forward. If you plan to be at SupplySide West, be sure to attend this important workshop!

In addition to Rick, lawyers Alan Feldstein and Jay Manfre will be attending SupplySide West to meet with current and prospective clients in the natural products and dietary supplement spaces.

To arrange a meeting with the Supplement Counsel team, email Rick Collins at Rcollins@supplementcounsel.com.

FDA WARNS TOTAL NUTRITION, INC.

FDA inspected Total Nutrition's Farmingdale location from March 6, 2017 through April 24, 2017. The investigation led to a host of issues including violations of cGMP regulations, which in turn resulted in the dietary supplements manufactured at that location to be deemed adulterated under 21 U.S.C. § 342(g)(1). Following the investigation FDA noted its observations on a Form 483, which Total Nutrition responded to on May 1, 2017.

Further, on June 29, 2017, FDA reviewed Total Nutrition's company website and another website where its products were being sold, along with the labels of 13 products sold on those sites. FDA determined that the claims on the websites and/or the product labels establish that the products are

drugs because they are intended for use "in the cure, mitigation, treatment, or prevention of disease."



FDA also noted a laundry list of issues with the products labels not complying with 21 CFR 101.36 and 21 CFR 101.9(c). This is yet another example of why it is critical to engage regulatory counsel to review your labels and GMP policies to ensure compliance with the regulations.

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm572479.htm>

WHAT SERVICES DOES CGMB OFFER?

In the ever-changing landscape of the health, fitness and nutrition industries, you need to stay ahead of the curve. Could you survive an investigation of your products, your labels, or your advertising copy? How do you navigate the maze of new regulations ... and run your business at the same time? With FDA policies actively evolving, how can you bring a New Dietary Ingredient to market in compliance with DSHEA? How can you ensure your advertising complies with FTC regulations? What must you do in order to comply with the dietary supplement cGMPs?

Collins Gann McCloskey & Barry, PLLC (CGMB), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CGMB offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to established organizations. CGMB offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CGMB have been formally rated by the professional legal community as practicing at the highest levels of skill and ethical integrity (AV-rated in Martindale-Hubbell). CGMB can help you stay ahead of the curve.

- Are all your product names and intellectual property protected?
- Have your product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Are all your ingredients DSHEA-compliant?
- How can you bring a New Dietary Ingredient to market or obtain GRAS status?
- Do you have SOP's for recording and reporting Serious Adverse Events?
- How can you substantiate your claims to satisfy FDA, FTC, and other federal and state regulatory agencies?
- Do you have proper insurance coverage and SOP's for customer complaints?
- Have you received a Civil Investigative Demand from the FTC?
- Have you been served with a Class Action suit? How would you handle one?
- Could you survive a 483 inspection?
- Could you survive an investigation of your facility, products, labels or claims?
- Are you fully compliant with cGMPs?

*The best time to ensure compliance with the law is up-front, before there's a problem!
Feel free to call us at (516) 294-0300*

CGMB - SELECTED FIRM PROFILES



Rick Collins, Esq., is based in New York and provides advice to some of the top names in the sports nutrition industry, and is the legal advisor to the International Society of Sports Nutrition and the International Federation of BodyBuilders. He has defended dietary supplement and sports nutrition companies against claims of distribution of misbranded or adulterated products and against serious criminal investigations by FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in numerous federal courts.



Alan Feldstein, Esq., an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CGMB. He is responsible for advising some of the firm's biggest clients in the sports nutrition industry and has extensive experience with contracts, copyright and trademarks, label and advertising review, supplement fact panel review, claims substantiation and assorted regulatory issues. He brings with him more than a dozen years of advertising and marketing law experience and continues to serve on the adjunct faculty of Southwestern University School of Law.



Jonathan Manfre, Esq. (Jay), is an associate attorney at Collins Gann McCloskey & Barry PLLC. He graduated from New York Law School in June 2015. Jay has been weight training for over twelve years, has competed in two bodybuilding competitions, and has been a consumer of dietary supplements since the age of 18. He is extremely familiar with the regulations of the dietary supplements/sports nutrition industry and very knowledgeable when it comes to effects and function of these supplements.

For more information about CGMB, industry news and updates visit www.supplementcounsel.com.

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