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Health & Fitness Supplement News

Volume 12, Issue 2 — *A Journal for Industry from CGMB* — Fall 2016

FDA Releases New NDI Draft Guidance

by David Torreblanca

In August 2016, five years after FDA released its first New Dietary Ingredient ("NDI") draft guidance, FDA issued its long-awaited revision. FDA replaced the previous draft after receiving sharp industry and Congressional criticism. The new draft shows that FDA accommodated some industry concerns, but rejected others outright.

Generally, a dietary supplement containing an NDI—a dietary ingredient that was not marketed in the United States before October 15, 1994—is adulterated unless: (1) the product "contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered" or (2) the supplement firm notifies FDA 75 days in advance of marketing the supplement in the United States, providing information showing the product "will reasonably be expected to be safe."

FDA's NDI draft guidance is aimed at clarifying many of the ambiguities and nuances in the law. Here are a few highlights from the new, 102-page NDI draft guidance:

- Master File: One notification may provide a variety of conditions under which the NDI may be used, which could eliminate or ease the burden of duplicative NDI notifications.

- Synthetic Ingredients as Dietary Ingredients? While holding fast to its position that synthetic copies of botanical extracts are not "extracts," FDA acknowledged that such substances may qualify as dietary ingredients under other provisions of the law—e.g., as dietary substances for use by man to supplement the diet by increasing the total dietary intake.

- "Old Dietary Ingredient" Lists: FDA rejected the authority of current "old dietary ingredient" lists, but stated that it will compile a list of ingredients marketed prior to October 15, 1994.

Whether an ingredient is an NDI and whether it requires a notification are important questions with significant legal implications. Selling adulterated products could lead to market withdrawals or recalls, as well as significant expenses and potential criminal prosecution. **Please call us with any NDI questions you have at 516-294-0300.**

True cGMP Compliance Includes Finished Product Testing

By Elan Sudberg, CEO, Alkemist Labs

While there has always been a testing component to cGMP compliance for dietary supplement marketers, New York Attorney General Eric Schneiderman brought it front and center last year. As a testing lab in the industry, we had seen cGMP compliance steadily improving, but Schneiderman's attention created interest in understanding the nuts and bolts of testing.

One emerging issue is complicated formulas and how to best test them. Testing methods have been slow to evolve in comparison to the innovation driving new product development. Most of our steady growth is simply confirming the ID of starting ingredients; however a quickly growing sector is finished products.

Manufacturers are mandated by law to perform many tests to assure identity, purity and potency, but the common test methods are mainly developed for simple plants and not new forms. If we only traded in powdered plants mixed together, testing would be much easier. That is not the case. Dietary supplements have come a long way from simple blends of herbs, water and minerals to today's designer proteins, complicated amino acids and jungle fruit flavorings.

We can test Camellia sinensis (green tea), confirm its genus and species, and confirm the quantity of caffeine in it without issue. The moment that green powder is mixed with another, the methods used to ID the green tea and to quantify the caffeine are no longer valid. The FDA has sided this way a number of times, but they don't have enough boots on the ground to address this very complicated and potentially litigious issue of finished product verification.

Only ~10% of our finished product customers have been interested in having methods developed to prove what is on the label is in the bottle. Focusing on ingredient supplier accountability will help improve overall industry quality, but it will not reflect upon the finished product. Every finished product should have some method development and ingredient verification analysis performed upon it.

cGMP compliance of the "we can get away with the minimum" mindset is a very real danger to the survival of your business. Regulatory agencies, investigative reporters, AGs, researchers and companies that have made a business out of dietary supplement sting operations, are all looking for their next target. They get headlines; you get a $250,000 legal and crisis PR bill.

We encourage formulators to budget test methods development into the project. Working with a lab accustomed to this process can make it a lot less painful.

As one of the industry's premier specialized testing labs, Alkemist Labs has assisted thousands of natural product companies approach, achieve and maintain cGMP compliance. Alkemist renders comprehensive analytical testing solutions to its clients in the Food & Beverage, Nutraceutical and Cosmeceutical Industries to meet their product safety, transportation and quality guidelines.

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 GMP's?

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 CGM&B. 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.

David Torreblanca, Esq., joined CGMB's dietary supplement practice group to serve the day-to-day legal needs of clients in the fields of sports nutrition, health, and dietary supplements. David earned a degree in psychology from Providence College, and he graduated magna cum laude from St. John's University School of Law. David has an in-depth understanding of FDA and FTC regulatory law and excels at label and claims reviews. He regularly helps clients respond to FDA warning letters and threatened class action litigation.

Robert Danko, Esq., is based in Southern California and serves Of Counsel to CGMB. He concentrates in the area of GMP regulations and FDA compliance. With decades of experience representing food and beverage manufacturers, he provides important legal guidance to CGMB clients, including responses to 483 notices and FDA Warning Letters. A graduate of Pepperdine University in Malibu, he received his law degree from Western State University College of Law and has been a member of the California State Bar Association since 1988.

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

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