

## **Alan Feldstein: American Herbal Products Association Webinar**

In November of 2004, almost 7 years ago I testified in front of FDA about the NDI process. As part of those comments I stated that in order for the NDI process to work FDA must adhere to a reasonableness standard as was intended by Congress

One of the areas where I believe FDA has not taken a balanced approach to the NDI issue in its guidance document is in response to the question set forth in Section IV(C)2 which questions if another manufacturer or distributor has already submitted a notification for a particular NDI and another party wishes to market a product with the same NDI, should an additional NDI notification also be submitted.

Note that the guidance provides that a NDI notification is product-specific, similar to the way a new drug application is product-specific. As the guidance now reads if a firm wants to market a product containing a NDI, and the ingredient does not meet the food supply exemption, it must file a notification even if other firms have already filed notifications for the exact same ingredient. As I read the guidance FDA would also require a NDI for an ingredient that is already permitted to be marketed if there is any change in the daily intake level or if the company changes the manufacturing process.

And while the law states that a manufacturer or distributor has to file a NDI notification for the supplement product that contains the NDI, the intent is to make sure specific ingredients are safe. It is an impossible burden to take into account every possible interaction of an ingredient or product. To take this example to its logical extreme this would mean that FDA could deny a NDI application because you don't know how your ingredient is going to interact with the milk or juice you used to consume your product. And I believe one could argue that these requirements would seem to effectively create a situation approaching drug approval and pre-market approval of supplement products containing NDI's. And that goes against the fundamental purpose and intent of DSHEA.

The guidance as now written would result in every company with a product containing the new dietary ingredient filing a NDI notification. If the NDI notification was a simple form, there might be little burden on industry. But the NDI notification process is time-consuming and expensive given what FDA has laid out in its guidance document as to what those requirements are to be.

Given the history of safe use of dietary ingredients, such requirements are burdensome and not reasonable.

This is especially true when put in the context of how industry functions, particularly in the area of sports nutrition where many products have the same ingredients. I say this for several reasons – both for industry and the FDA.



There is a cost factor in preparing the materials that FDA says it is going to require. An ingredient supplier who is going to market the ingredient to dozens of customers is better suited to amortize that cost. There is no logic in requiring each company to submit NDIs with virtually identical information for different products that contain the same ingredients. Further it creates a tremendous burden for FDA. Why should they have to look at 100 NDIs for the 100 customers that a supplier sells a single ingredient to?

While FDA may argue that they cannot be assured how each ingredient will interact with other ingredients, that risk is in reality, extremely low - so low as to be non-existent. First, if combining it with other ingredients caused the product to be unsafe it would present itself quickly and market forces and FDA's ability to remove unsafe products off the market are in place. I would challenge FDA to look at its AER reports and see if there is a statistically significant amount of SAERs that are derived from an ingredient that was safe in one product but not safe in another.

Such a requirement is analogous to having an ingredient affirmed as GRAS for a lemon beverage and then having to seek reaffirmation the ingredient is GRAS for a cherry flavored or lime flavored beverage. It just does not make sense.

My firm will be filing comments on a variety of issues, including this one but I also encourage all those listening to also raise this issue, particularly the ingredient and raw material suppliers, as this may affect you most.

If FDA truly wants to work with industry and have companies comply then it would be a much more efficient system to have the ingredient suppliers file NDI notifications for their ingredients and then allow their customers to rely on those NDIs for including the ingredients in their supplements, even if the supplements contain other new dietary ingredients that require a notification.

## About Alan Feldstein

Alan Feldstein brings with him more than twenty years of advertising and marketing law experience and more than ten years in the dietary supplement industry. Alan's expertise is such that he serves as a professor of law on the Adjunct Faculty staff at Southwestern University School of Law, teaching advertising and marketing law.

Alan's legal career began as a **successful civil trial lawyer prosecuting business litigation cases for his clients**. Alan then joined and became a partner in a New York advertising and marketing law firm representing film, television, and music clients, business clients and advertising agencies, direct response television clients, marketing firms and advertisers. Known for his negotiating skills and business acumen, Alan's clients always have appreciated his business perspective on resolving legal issues affecting their business in an efficient and cost effective manner.

In 1997, at the request of one of his clients, Alan became general counsel for a dietary supplement company and was part of the management team that took the company to over 150 million dollars in annual sales.

In addition to this work, Alan was the catalyst for putting together several industry associations in their ongoing effort to educate the public, legislators and administration officials on the facts and science regarding dietary supplements containing ephedra. In that capacity Alan flew over a million miles meeting with officials in Washington, D.C., and state capitals around the country. His unique ability to reach consensus, convey complicated issues in simple terms, draft legislation, work with legislators and agency officials and advising companies on how to convey their messages in a positive and effective manner have garnered him respect in the industry.

**He also has extensive experience in assisting nutritional companies with contracts, copyright and trademark, litigation supervision, claim substantiation and regulatory issues.**

As a result of all this experience and his extraordinary qualifications, Alan was selected by Collins, McDonald & Gann, P.C., to become Of Counsel to the firm and assist CMG clients in complying with the constantly changing, ever challenging maze of rules and regulations affecting nutritional companies. Alan is personally responsible for advising some of CMG's biggest clients in the supplement industry.

**His location in southern California provides CMG with a presence on both coasts.**

