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Functional Foods and Dietary Ingredient Safety Considered at FDLI Conference

On September 10, 2013, the Food and Drug Law Institute ("FDLI") hosted a conference, "Safeguarding the Functional Food and Dietary Ingredient Supply Chain". The Conference concerned a variety of emerging requirements and compliance issues for functional foods and dietary ingredient or supplement manufacturers and distributors in view of the FDA Food Safety Modernization Act ("FSMA"). Signed into law on January 4, 2011, FSMA has been called "the most sweeping reform of our food safety laws in more than 70 years." Among other things, FSMA shifts the focus from responding to contamination to preventing it to ensure the U.S. food supply is safe.

The Conference Keynote, Daniel Fabricant, Ph.D., FDA's Director, Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine, remained throughout the program and provided insights regarding FDA's view on "functional foods" and dietary ingredients. First off, FDA has not officially recognized that there are "functional foods", despite understanding that many people are self-treating based on information gleaned on the Internet or elsewhere with the hopes to either prevent or mitigate potential or current health issues. According to Fabricant, while dietary supplements may make certain health (structure/function) claims with adequate scientific evidence, FDA does not authorize foods to make health claims; instead, FDA considers foods to make statements about taste, aroma, and nutritive values.

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In Fabricant's view, it is not clear where industry should go when looking for guidance on functional foods, which are viewed by industry as foods with legal structure/function claims. FDA is concerned about the potential for harm: (1) invisible (hard to detect), (2) conscious (deliberately tainted), or (3)

catastrophic (affects many people). Fabricant suggested that energy drinks, for example, have been suggested as a functional food, but many of these products include caffeine, which is a drug or conventional food. But the physical attributes of the product is not the primary determinant. Here, FDA is developing guidance to distinguish liquid dietary supplements from conventional, food-type beverages. What FDA has seen is that companies engage in "category hopping" to pick the category that where they best meet the requirements, but good manufacturing practices ("GMPs") often remain an issue. And in FDA's view, many products over rely on "bad" information rather than "competent and reliable scientific evidence." Here, FDA looks whether a particular claim is substantiated-- what is the meaning of claim, the relationship of scientific evidence to the claim, the quality of evidence, and the totality of evidence in view of the claim. The biggest "pitfall" Fabricant mentioned is an over-reliance on disease treatment studies and confusion regarding intended use.

Fabricant reported that FDA inspections (core functions to inspect and test) in this area have increased since FSMA (2011), from 84 inspections in 2010 to 175 inspections in 2011, 341 inspections in 2012, and about 400 inspections expected in 2013. Of these, about 70% of the inspected companies required some corrective action, suggesting there is an industry-wide quality issue. As part of the quality initiative, finished product manufacturers are expected to conduct diligence and audits of their food ingredient suppliers with more sophisticated testing that depends on intended use. FDA will look to its inspectors and potentially third-party auditors to help guide the process to identify the best "targets" to inspect to ensure that dietary ingredient suppliers are compliant with cGMPs and the new requirements under FSMA, which apply not only to foods but also dietary supplements and dietary ingredients.

A fundamental issue that emerged during discussion was the development of appropriate specifications for manufacturers and raw material suppliers from ingredients or additives derived from foods to follow. According to Fabricant, dietary ingredient and food manufacturers should be able to figure out the relevant specifications, which are driven in part by intended use and what risks need to be addressed, depending on the product and supplier.

During the Conference, a variety of consultants, commentators, and a dietary ingredient manufacturer offered their views on what FSMA and FDA's draft regulations or guidances promised to offer in terms of safety assurances and requirements and how appropriate standards may be developed. Currently, there are two main new proposed regulations to emerge from FSMA that both issued on July 29, 2013 and were discussed during the Conference: "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" and "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications". Both of these proposed rules will be considered in an upcoming FDA Public Meeting on September 19-20, 2013, announced here. In addition to this Public Meeting, FDA plans to hold two additional meetings on these FSMA proposed rules.

During the Conference, Stephen F. Sundlof, D.V.M., Ph.D., former FDA Director of the Center for Food Safety and Applied Nutrition (2 years) and the Center for Veterinary Medicine (14 years) and current Senior Advisor for Animal and Human Food Safety, EAS Consulting Group, delivered a presentation, "Best Practices: Where Industry Should Lead on Ensuring Proper Testing & Auditing". Jason Brocks, a Legal Analyst for Bloomberg L.P., advocated that industry take a more proactive role to develop global safety standards that can be endorsed by world regulatory authorities, rather than waiting for the next catastrophe or health crisis to mandate additional requirements. Ben A. Firschein, Director, United States Pharmacopeia ("USP"), described USP's view of standardizing dietary ingredients and dietary supplements.

Prior to a "Take-Away" roundtable discussion, Weiguo Zhang, President and COO, Synutra International, Inc., presented his company's experience with addressing "economically-motivated

adulteration" with one of their key dietary supplement ingredients, chondroitin sulfate ("chondroitin"). Chondroitin dietary supplements are a top-5 seller with annual sales of about $1 billion, and the United States imports about $100 million raw chondroitin material, which is derived from bovine, porcine, or avian cartilage sources. Zhang explained that his company uncovered that the most commonly used chondroitin assay test (a high performance liquid chromatography ("HPLC")-enzymatic test) could not detect certain adulterated ingredients that were being used by other chondroitin dietary ingredient suppliers. Working with FDA and USP, Synutra developed a relatively inexpensive and simple electrophoresis test (USP 726) to detect adulteration of chondroitin sulfate. Zhang reported, however, that to its knowledge, other chondroitin dietary ingredient manufactures have not adopted the test, perhaps because they are unfamiliar with using electrophoresis tests. From Zhang's perspective, until the new test is mandated by the industry, there will continue to be adulterated chondroitin dietary supplements, which will continue to make it difficult to determine the clinical results from more pure sources. From his perspective, the dietary ingredient industry needs to invest in quality and supply chain integrity to make cGMP compliance requirements work with valid verification programs.

The conference concluded with a roundtable discussion and FDLI plans a follow-up meeting next year to revisit these topics when FDA finalizes its proposed regulations.

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