Note from the Chair by Suzan Onel

I’m pleased to announce the inaugural issue of the ABA’s Food, Cosmetic, and Nutraceuticals (“FCN”) newsletter. In this issue, we hear from Professor Neal Fortin on the importance of food law education, editor Charles Woodhouse on preparing for the Food Safety Modernization Act, and editor Kelly Lightfoot on the differences between dietary supplements and conventional foods. These articles are intended to educate, encourage discussion, and prompt closer scrutiny. Whether your role is legal counsel, food scientist, regulatory affairs, or public policy, our hope is that this newsletter will offer something for each of you.

Preparing for the Food Safety Modernization Act (FSMA) by Charles F. Woodhouse

In this brief essay we will discuss the role of the practicing “food lawyer” in preparing her or his clients for the sweeping changes in the regulation of the US food supply which will be introduced over the next several years. This author, then an MS-candidate graduate student at Michigan State University, spent 2010 watching the FSMA move through Congress and wondering if his chosen thesis topic – the implementation process for the Act – would become irrelevant if FSMA died in Congress. That did not happen. President Obama signed the FSMA, and this grad student finished his MS Food Safety thesis in 2011. (Sections of the thesis are available on the author’s Food Law Blog.)

Our firm’s clients are primarily in the Aquatic Food Products (Seafood and Aquaculture) industries and in the Produce Industry (primarily importers as well as some domestic producers). Given that nearly 50% of serious Food Safety regulatory problems, in both Europe and the USA, are in these two sectors, specialization in these two industries made sense to us, particularly in view of the author’s executive experience in both sectors.

Future newsletters will be issued on a quarterly basis and will span domestic and international topics related to food, dietary supplements, medical food, and cosmetics. We invite you to enjoy these articles and consider submitting your own. A list of potential topics appears at the end of the newsletter, but we would welcome other ideas as well. Cheers! ♦

At the time of this writing, mid-October 2013, as our readers know, we are in the comment periods for the Proposed Rule on Risk-Based Preventative Controls (RBPCs), the Proposed Rule on Produce Food Safety, and the Proposed Rules on the Foreign Supplier Verification Program (FSVP). (See posts of relevant documents on our Food Law Blog pages dated January 5, 2013 and July 26, 2013.)

In the Food Import sector, we now await FDA’s release of the Proposed Rule on the Voluntary Qualified Importer Program (VQIP). One major problem is that the FSVP and the VQIP are like a “pair of scissors”. FDA has given us only the FSVP and not the VQIP so we really do not know how to appropriately comment on the FSVP. Also they have completely failed to give us any guidance on the HACCP exemption in the FSMA for seafood. It is fine for FDA to say that seafood will remain in HACCP, but how will we qualify for VQIP if we do not prepare a RBPC? Many of us are unhappy to face the possibility that the FSVP Comment Period may end before we are permitted to review the VQIP Proposed Rule.

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Earlier this year, Rockstar Energy ("Rockstar") and Monster Beverage Corp. ("Monster") changed the labeling and marketing of its energy drink products. The companies announced their decisions mere months apart that they would no longer be marketing these products as dietary supplements but would instead be marketing them as foods. Many consumers will likely not notice the change or appreciate exactly what it means to the regulatory status of these wildly popular energy products. Furthermore, many consumers do not realize the extensive decision-making process that companies like Monster and Rockstar engage in when determining whether to market their products as foods or supplements. Here we will explore this decision-making process, the difference between foods and supplements, and why the difference matters in the grand scope of federal regulation and consumer perception.

**Supplements and Foods: What’s the Difference?**

What is the difference between a dietary supplement and a food (sometimes referred to as “conventional foods”)? To answer, we could turn to the Federal Food, Drug, and Cosmetic Act ("FDCA"), the statute giving the Food and Drug Administration ("FDA") authority to regulate supplements and foods. The FDCA defines a food to mean “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” While a little self-evident (it is obvious to most that food is an article used for food), this definition is straightforward. The definition of “dietary
**FSMA from page 1.**

It is certain that these rules, once completed with the release of the VQIP, will make substantial changes to food import regulation and procedure and keeping up to date on these changes will present major challenges for food lawyers.

We note that major retail grocery and food service buyers are suddenly worried about FSMA compliance issues and are beginning to require extensive documentation from their suppliers. In recent months, Food Importers have started coming to us with questions, now that their retail grocery and food service customers are demanding detailed Food Safety Packages including guarantees with very broad indemnification language. This is particularly evident in the Produce sector (because of recent major Food Safety incidents), but, increasingly, buyers are setting extensive documentation requirements in other food categories as well.

Based upon what we are seeing from our clients, here are a few comments on what you should be doing now to prepare your clients for FSMA compliance:

1. Your clients will need to retain counsel competent in drafting required FSMA documents over the next several years. This is the time for you, the attorney, to go back to the books and study. We cannot recommend any specific program, but I can confirm that at least three US research universities offer Certificate Programs in Food Regulation.

2. You need to think carefully about privilege issues and counsel your clients to be careful to compartmentalize the role of consultants, since your client’s communications with consultants are not privileged. Serious Food Safety incidents can quickly develop into civil litigation, and even into criminal prosecution. Our firm has recently seen several other sophisticated clients propose “Recall Plans” that unnecessarily involve too many clerical level employees and outsiders in their “Crisis Management” group. These companies believe that “sharing” information with lots of people is “good”. To the contrary, a properly designed Recall Plan must include strict compartmentalization of information and active protection of attorney-client privilege.

3. If your client is a food importer, this third point is very important. While we wait for the FSVP and VQIP Proposed Rules, you should have already drafted for your client its Recall Plan documents, its Supplier Questionnaire, and its required Guarantee Document Package. The Supplier Questionnaire is essential for the timely gathering of the technical information that will be required in the RBPC Plan document that your client will soon be required to prepare.

4. Since we already have, from the text of FSMA and from the Proposed Rule, a nearly complete understanding of what will be required for RBPC documentation, your clients already should have been in contact with their domestic suppliers on RBPC preparation. Remember, we are talking about not only the basic food products themselves, but also all minor food ingredients, food additives, food allergens, processing aids, and food-contact materials.

5. As mentioned above, you must be particularly attentive to Guarantee and Warranty Agreements that your clients are asked to sign from downstream customers. Very few practicing lawyers are familiar enough with Food Law in general, and the FSMA in particular, to competently produce such document without making fundamental errors. We have seen many such documents which contain language that violates Product Liability coverage terms and conditions and that clearly demonstrate inadequate knowledge of basic insurance law and procedure (including completely inappropriate choice of counsel provisions). Also, we have seen that many such Guarantees and Warrantys are routinely signed by sales executives who are not competent to review such complex documents. All Food Safety Guarantee and Warranty Agreements must be reviewed by competent counsel. Your clients should be warned not to permit sales executives to sign Guarantee and Warranty Agreements that may bind the company to impossible promises.

6. Finally, three more points on Recalls. First, it seems that few lawyers think to include language that obligates the upstream supplier to timely notify your client when a Recall event involving that supplier’s product initiates from another customer of that supplier. Secondly, we have seen very few documents (including Recall Insurance riders) that adequately define and present the alternatives to

Please see FSMA on page 4.
Recalls – Market Withdrawals and Stock Recoveries. Third, remember that many products entering US distribution channels will end up in retail in Canada. Be aware that there are many differences between US and Canadian Food Regulation – the differing lists of Major Allergens is but one small example.

7. If your clients are importers, they already should have been in touch with each of their suppliers to plan for FSVP and VQIP compliance. This is an area where the “You snooze, You Lose” rule applies. If your client is an importer who is behind the FSMA implementation curve, she may well find herself playing second-fiddle to one of her competitors who “gets it” and is using FSMA compliance as a tool to expand his or her business.

8. We are concerned by the “whistleblower” provisions of Section 402 of the FSMA. We think that clients need to be carefully counseled on Section 402 and on its relation to the Reportable Food Registry. We view this as an area of significant danger to clients.

9. The Product Liability provisions in your client’s CGL Policies must be carefully reviewed. If your client does consider Recall Coverage, you must review covered events and exclusions. In a recent lecture, this author handed students a redacted Recall Insurance rider. The students had a great deal of trouble understanding what benefit this coverage would actually bring given the items on the exclusions list.

10. The Mandatory Recall and Administrative Detention Authority given to FDA by Congress in Sections 206 and 207 of the FSMA will also be a source of significant concern to counsel to both food importers and to domestic food producers, distributors, and retailers. This author believes that Section 206 and 207 will present significant problems in relation to Article 9 Security Interest perfection in secured transactions. What will happen in circumstances under which FDA uses Mandatory Recall or Administrative Detention Authority against inventory in which an Article 9 security interest exists and upon which a secured lender relies?

11. Looking at these Issues from the Overseas Supplier’s Perspective - Food Exporters from around the world will be under great pressure to meet FSMA goals and requirements in the next several years. They will be forming stronger links with US importers who can help them. I am counseling my clients that, in the new era of Food Safety, importers who sit passively and let the world change around them may wake up and find that they have been left behind. ♦

**Beverage Products from 2.**

supplement” added by the Dietary Supplement Health and Education Act (“DSHEA”) is more complex. The FDCA states that a supplement must be “intended to supplement the diet” and must contain “one or more” of specific dietary ingredients: vitamins, minerals, herbs or other botanicals, amino acids, “a dietary substance for use by man to supplement the diet by increasing the total dietary intake,” or “a concentrate, metabolite, constituent, extract, or combination of any” of these types of dietary ingredients.3 Additionally, the statute requires that supplements not be “represented for use a conventional food” and that supplement be “labeled as a dietary supplement.”4

Based on these definitions, it would seem to most consumers that supplements are merely more specialized versions of foods. In other words, supplements are foods that are consumed for a specific purpose, “to supplement the diet.” The supplement definition is interesting for a few reasons. Under DSHEA, a supplement is still a food under the FDCA but a supplement becomes

**Please see Beverage Products on page 5.**
Beverage Products cont’d.

a special subset of foods subject to specific requirements related to labeling, manufacturing, formulation, and claims. There are essentially four criteria that a product must meet in order to be deemed a dietary supplement under DSHEA. First, the supplement must contain an appropriate ingredient that could supplement the diet. Next, the product must be intended for consumption by humans. Also, the product must “not be represented for use as a conventional food or as a sole item of a meal or the diet.” Lastly, the product must be labeled as a dietary supplement. There are many beverage products on the market today purporting to meet all of these requirements. However, FDA has cited growing concern regarding these types of products.

The FDA has never specifically announced whether these beverage products, like those sold by the energy drink industry should be regulated as foods or supplements. As demonstrated by Monster and Rockster, energy drink manufacturers have marketed their products as either dietary supplements or conventional beverages, depending on how they choose to label and market the products and the ingredients they choose to use. While never specifically placing these products in a particular category, FDA has issued a draft guidance entitled “Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods” in December of 2009.

For most FDA-regulated products, FDA determines how a product is regulated based on the product’s intended use. If a product bears claims that it supplements the diet, it will be deemed a supplement by FDA. If the product bears claims that the product should be consumed for its taste or nutritive value, FDA will regulate the product as a food. However, in discussing the background of the Guidance, FDA noted that it was concerned about the trend of marketing beverages as dietary supplements, “in spite of the fact that the packaging and labeling of many liquid products represent the products as conventional foods.” FDA went on to note that even if a product label states the intended use of one of these beverages to be as a dietary supplement, “the product may in fact not be a dietary supplement.” FDA went on to list factors that determine whether the product is actually a conventional food even when labeled as a supplement, including “packaging, the volume in which they are intended to be consumed, their product or brand name, and statements about the product in labeling or advertising.” As an example, “the packaging of liquid products in bottles or cans similar to those in which single or multiple servings of beverages like soda, bottled water, fruit juices, and iced tea are sold, suggests that the liquid product is intended for use as a conventional food.” Additionally, FDA went on to state that when products bear words like “beverage,” “drink,” “juice,” or other words that are commonly used in conventional foods labeling represent the product as a conventional food. The FDA’s position in this Guidance establishes that FDA is looking to more than a product’s stated intended use when assessing the product’s regulatory status and is making its own assessments of the product’s implied intended use.

Furthermore, FDA’s Guidance cited a concern regarding the ingredients appearing in these liquid products. While dietary supplements can include ingredients, called dietary ingredients, in their formulations that were marketed in the U.S. prior to October 15, 1994 in or as a dietary supplement, conventional food products can only include ingredients that are either approved food additives or generally recognized as safe (“GRAS”) by qualified experts. Therefore, an ingredient that qualifies as a dietary ingredient permissible for use in dietary supplements may not be an approved food additive or GRAS and not permissible for use in a food and vice versa. In January 2010, FDA issued a Warning Letter to Innovative Beverage Group, Inc. (“Innovative”) regarding its beverage product, “Drank.” Innovative labeled and marketed Drank as a supplement for relaxation. However, FDA determined that the

Please see Beverage Products on page 6.
Beverage Products cont’d.

product was implicitly intended to be a conventional food, likely due to its packaging (in an aluminum can) and its use of the words “beverage” and “drink” throughout its marketing. In its Warning Letter, FDA stated that Drank was adulterated because it contained melatonin which was not GRAS or an approved food additive and, consequently, contained an unapproved food additive causing the product to be adulterated under the FDCA. This Warning Letter displays FDA’s recent policy regarding both intended use and the use of ingredients in these liquid dietary supplement products. FDA has several enforcement tools in its arsenal to handle such adulteration and misbranding violations, ranging from Warning Letters like the one issued to Innovative as well as injunctions or criminal charges, depending on the severity as deemed by the agency.14

Impact on Industry

Until FDA issues the final draft guidance on beverages and liquid supplements, the industry and consumers will be left in the dark regarding how these products should be regarded and regulated. There have been several recent, widely publicized adverse event reports received by FDA of injuries and deaths claiming that Monster Energy, 5-Hour Energy, and Rockstar Energy drinks were involved. All of these products were marketed as supplements at the time of the adverse event reports.15 In fact, in November of 2012, FDA announced it would be investigating “reports of illness, injury or death of people who took products marketed as ‘energy drinks’ or ‘energy shots.”16

With the safety of energy drinks questioned by consumers, the media, and politicians, there could be a public push for FDA to exercise more regulatory oversight over these products. At this time, it remains unclear as to the direction that will be taken as legitimately marketed liquid energy supplements could be majorly affected by such oversight. It also remains unclear as to how FDA will balance industry innovation and consumer safety as it keeps up with the ever-changing supplement and food industries as they grow and develop new and novel products and marketing strategies.

Endnotes
2 21 U.S.C. § 321(f) (FDCA § 201(f)).
3 21 U.S.C. § 321(ff)(1) (FDCA § 201(ff)(1)).
4 21 U.S.C. § 321(ff)(2) (FDCA § 201(ff)(2)).
5 FDA’s “Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods,” available at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm192702.htm (Dec. 2009). The FDA’s Guidance has not been finalized at this time. However, the U.S. Government Accountability Office stated in its March 2012 report that the FDA is developing and reviewing a final guidance document clarifying when a liquid product should be marketed as a dietary supplement or conventional beverage. Available at http://www.gao.gov/assets/660/653113.pdf.
6 See United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969), holding “It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source.” 7See FDA’s “Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods,” supra.
8 Id.
9 Id.
10 Id.
11 Id.
12 21 U.S.C. § 321(s) (FDCA § 201(s)).
14 21 U.S.C. §§ 331(a) and 342(a)(2)(C) (FDCA §§ 301(a) and 402(a)(2)(C)).
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factors, a number of complicated matters face our regulatory agencies, such as nanotechnology, genetic engineering, and cloned animals.

All these factors focus attention on the food regulation landscape. In short, never has there been a greater need for interdisciplinary scholarship and education on food law. Not only must food scientists learn about food law, but also lawyers in the field must learn about food science. It is critical for food businesses to have legal professionals who understand the complexities of today's food laws and regulations.

Most will not receive this interdisciplinary education when they received their law degree so they will need to seek out continuing education. Some of this will come at seminars, workshops, and conferences. However, as good as this “flood irrigation” approach can be for acquiring a large amount of information quickly, there is nothing that can replace the semester long “trickle irrigation” of a college course.

To bring together the law, science, and policy education for professionals in the food law field today, distance education via Internet graduate level courses will fill the need. Michigan State University has a decade and a half of experience teaching food law courses via the Internet through its Institute for Food Laws and Regulations.

Michigan State University College of Law recently partnered with the Institute for Food Laws and Regulations to create a new online graduate program in global food law. Michigan State University College of Law's online Master of Laws (LL.M.) and Master of Jurisprudence (M.J.) degree programs in global food law are designed for lawyers and other professionals working in the food and agriculture industries, food safety, law, government, and other areas involving international food law.

The LL.M. program is aimed at students who have earned a Juris Doctor (J.D.), Bachelor of Laws (LL.B.), or other comparable law degree. The M.J. program is designed for those who do not have a law degree, such as doctoral students in other disciplines, policymakers, government officials, business executives, scientists, and other professionals.

Students in the programs will benefit from the close alignment between the Law College and MSU's College of Agriculture and Natural Resources, which co-sponsors an International Food Law Internet Certificate Program with the University’s Department of Food Science and Human Nutrition.

In our growingly complex and interconnected world, the timely transfer of scientifically and legally valid information and understanding is a crucial component of our infrastructure. Food lawyers and their leadership in this area are vital. Online courses for working professionals, throughout the nation and internationally, with play an important role in assisting the legal academy fulfill this important service.

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About the Editors

Charles F. Woodhouse is an Attorney and Partner, in the law firm of Woodhouse Shanahan PA. Charles is admitted to the Bars of Pennsylvania, Florida, and the District of Columbia. Charles earned his BA at Dartmouth, MBA at Wharton (University of Pennsylvania), JD at Rutgers, and his Graduate Certificate in International Food Law & Regulation and MS Food Safety at Michigan State. His MS Food Safety thesis at MSU received MSU’s 2011 Mather Food Safety Award.

He is Adjunct Professor of Law at MSU College of Law and is currently teaching Regulation of US Food Imports for the 2013 Fall Semester. His business career includes being a founding shareholder of Marine Harvest International (salmon, shrimp, and other fin-fish aquaculture) and service as its president during its years as a publicly traded company on the American Stock Exchange. Since 1999, Charles has devoted his full time to his law practice which specializes in regulatory matters affecting the seafood and produce industries which together account for nearly 50% of all Food Safety incidents in the USA and the EU. His Food Law Blog may be found at www.food-label-compliance.com and his law firm’s website is www.seafood-and-produce-law.com and he can be contacted by email at cfw@regulatory-food-science.com.

Charles divides his year between Scanno (Aquila) Italy, Atlanta, Georgia, and Cedar Key, Florida. His law practice includes European Union Food Industry Regulatory Compliance with a particular focus on EU Food Labeling Regulation.

Kelly L. Lightfoot is an attorney with the Food, Drug, and Life Sciences Practice Group at Fuerst, Ittleman, David, & Joseph, PL in Miami Florida. Kelly focuses her practice in the areas of food and drug law, assisting clients with regulatory and legal compliance issues involving the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and other federal, state and local authorities. Kelly is originally from Columbus, Ohio and earned her bachelor's degree in English from The Ohio State University and received her JD from Cleveland-Marshall College of Law.

Kelly has extensive experience representing clients in various federally regulated industries, including the medical device, food, dietary supplement, cosmetic, veterinary products, over-the-counter drug, and human cells, tissues, and cellular and tissue-based products (HCT/Ps) industries. She has assisted clients with product development, formulation, manufacture, importation and exportation, distribution, and marketing.

Kelly has authored and co-authored articles in various publications on the topics of dietary supplements, conventional foods, veterinary drugs, and medical device regulation. She advises clients on food, supplement, and cosmetic labels and labeling, advertising, social media, formulation, and manufacturing in compliance with FDA and FTC regulations and policies. Kelly can be reached by email at klightfoot@fuerstlaw.com.
Invitation to Submit Papers for FCN Committee Newsletter

The Editors of the FCN Committee Newsletter would like to extend an invitation to the Committee to submit papers for the Winter Issue of the Newsletter. Below is a suggested list of topics but please feel free to submit papers based on other current topics in the areas of food, cosmetics, and nutraceuticals.

- The relationship between the Article 9 Security Interests of lenders to food companies and FDA’s mandatory recall and administrative detention authority under the FSMA. What are the concerns of counsel for lenders during a serious (Class I or Class II) recall?
- Product liability insurance and the FSMA. How do you craft guarantee language that satisfies both the upstream and downstream lawyer in the supply chain?
- FDA Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition. What does this recently issued guidance document mean for the medical food industry?
- FDA regulation of cosmetics moving into 2014 and beyond. What are the regulatory trends and what issues will affect industry in the upcoming year and beyond as FDA takes a greater interest in cosmetic manufacturing practices and imported goods?
- Food, cosmetic, and nutraceuticals advertising. Given some interesting decisions and legal activity in the area of advertising this year, how should clients be advised when crafting advertising for their products?
- The role of third-party auditors in a comprehensive food safety plan and a cost-benefit analysis as well as the relation to insurance and liability issues.

The Winter issue of the Newsletter will be published in January, 2014 and the Editors ask that articles be submitted by December 31, 2013. Articles should be approximately 1,500 words. If you are interested in contributing please email the Editors, Kelly Lightfoot at klightfoot@fuerstlaw.com and Charley Woodhouse at cfw@regulatory-food-science.com.