Navigating the Emerging Regulatory and Litigation Challenges to the Food Industry

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Foreword

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In an atmosphere of aggressive challenges from consumer advocates, state attorneys general and the plaintiffs' class action bar, manufacturers of foods, beverages and dietary supplements face an often confusing and inconsistent body of regulations and common law requirements. These can have diverse consequences, depending on subtle distinctions in how a product is labeled or marketed. In many instances, such as when defining whether a manufacturer can claim that a product is "natural," the FDA has declined to provide any meaningful guidance. But even when the FDA does attempt to provide regulatory input, its "guidance" often adds confusion and the potential for missteps by those who strive to comply.

This report seeks to add clarity to the legal ambiguity in the Food Industry, addressing areas in which we see risk potential for manufacturers of foods, beverages and supplements. Some questions it attempts to answer include:

- What are the distinctions between beverages and supplements and the consequences associated with each?
- What are "added sugars" as opposed to naturally occurring sweeteners?
- What considerations should be made in deciding how and when to comply with FDA's new guidelines on reducing sodium content?

Our aim in working with members of the food industry is the same one as for manufacturers in all industries: to understand the client's business and challenges, find creative and efficient approaches to problems, and provide value in order to mitigate future risk and maximize business opportunities.

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sugars)

The Perils of Navigating Legal Issues in Bringing a New Food Product to Market

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The legal environment today does little to simplify the process of bringing a new food product to market, particularly when it comes to how that product will be labeled and marketed to consumers. Putting aside for this discussion issues relating to intellectual property concerns regarding the use of trade names and trade dress, and false advertising claims by competitors, the combination of evolving FDA regulations concerning food marketing and labeling and plaintiffs' attorneys looking for every opportunity to commence a class action suit over a company's marketing efforts makes it important for food and beverage companies to carefully consider how they describe their products.

One of the most notable areas in dispute is the question of when a manufacturer can use the term "natural" or "100 percent natural" in describing its product, given the likelihood that nearly every food product will contain ingredients that have been "processed" to some degree. To the purists—or more accurately, plaintiffs' attorneys looking for a basis to bring a lawsuit—the presence of any ingredients that are subject to any form of processing leads to the unreasonable conclusion that the use of a variation of the term "natural" is a false advertising claim subject to legal redress.

While many food company defendants have in the first instance argued that the FDA has "primary jurisdiction" over the appropriate use of the term "natural" and that as a result, such claims must be dismissed or stayed until the FDA takes a position on this issue, many courts have concluded that it is unlikely that the FDA will provide a definitive definition of "natural" any time in the near future. As a result, there have been some courts that have deferred to the FDA while others have permitted the plaintiffs to pursue their claims. Indeed, the FDA has so far declined to define what will and will not pass as an accurate statement that a food product is "all natural." In commenting on this issue, the FDA has stated that: "From a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth." The FDA has not objected to the use of "natural" if the food does not contain

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added color, artificial flavors, or synthetic substances, but it goes no further than that.

By declining to address all of the questions relevant to the "natural" issue, the FDA has left food companies with little guidance beyond the obvious "synthetic" and "artificial" criteria, and perhaps more important, with no clear defense to the claims of class action plaintiffs. For example, producers are facing claims that use of the term "natural" is deceptive if any of the natural ingredients of its products are extracted or refined, because, it is claimed, those ingredients are too highly "processed" to justify use of the term "natural." Similarly, there is heated debate in the courts and various state legislatures over whether ingredients harvested from naturally grown crops planted with genetically engineered seeds may still be referred to as "natural."

A related issue arises with the manner in which manufacturers refer to the sugar content of their products, when even statements that would be considered truthful and accurate to the reasonable consumer have become subject to claims of false and misleading product labeling and marketing. For example, in a case entitled *Rahman v. Mott's LLP*, a federal court in California recently ruled that claims may proceed against a popular brand of 100 percent apple juice for putting the statement "No Sugar Added" on its label. While most of us realize that fruit juice will naturally contain a relatively high amount of sugar, and this particular company accurately stated the sugar content of its juice on the product's Nutrition Facts panel, the plaintiff argued that the "No Sugar Added" statement created the false impression that this brand of apple juice contained less sugar than competing juice products.

Besides contending that the statement was true because it had not added any sugar to its 100 percent apple juice product and that the accurate amount of sugar naturally present in the juice was accurately stated on the Nutrition Facts panel of the product, the defendant juice company argued that the court should stay the plaintiff's claims because the FDA is currently reviewing its standards and requirements for the content of Nutrition and Supplemental Facts labeling. In particular, the FDA has proposed that the Nutrition Facts Label require manufacturers to disclosed the presence or absence of added sugar in addition to the disclosure of total sugar content. Nevertheless, the court determined that the issue of whether a manufacturer is providing false and misleading information when it includes a true statement that no sugar has been added to the product is unrelated to the FDA's current consideration of that very issue. The court based this decision on the premise that the FDA rulemaking proceeding deals only with the content of the Nutrition Facts label while the statement at issue appears in an area on the product other than in that Fact panel. So now the plaintiff will be entitled to pursue the class action claim that the true statement regarding the absence of added sugar is false and misleading.

While nearly all of this litigation has been pursued in California because it has what are likely the most stringently enforced consumer protection statutes in the country, the practical effect for most food companies will be that the outcome of the California litigation will drive the national marketing of most products, as evidenced by the number of companies that have revised their labeling in response to the litigation claims in California. Moreover, the examples discussed here are just a few instances of how our current legal environment makes it difficult for reputable food producers to honestly market and label their products without fear of legal repercussions.

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Sweet and Savory: Popular Ingredients with Possible Lawsuits

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Few ingredients are more common in American food products, or more popular with American consumers, than sugar and salt. Indeed, the average American consumes 3,400 milligrams of salt and 110 grams of sugar every day, amounts well in excess of those recommended in the Dietary Guidelines for Americans issued by the U.S .Department of Health and Human Services in conjunction with USDA. More than just popular, both ingredients are extremely useful to food manufacturers. Sugar, for example, allows for longer shelf-life while adding bulk and color to processed foods. The preservative effect of salt has been known for thousands of years, but salt also serves to reduce cost in comparison to other flavoring agents while masking unpalatable flavors associated with processing. Given this combination of utility for industry and popularity with consumers, there should be little surprise that both sugar and salt maintain a constant presence in the American diet.

For food manufacturers, though, the near future may hold a number of challenges where sugar and salt are concerned. In particular, recent U.S. FDA action implicating sugar and salt, combined with increased willingness on the part of plaintiff lawyers to pursue labeling and ingredient claims against food manufacturers, could lead to an environment of increased cost and litigation across the industry.

Will Sugars Lead to Litigation?

Following the passage of the Food Safety Modernization Act, or FSMA, in March 2014 the FDA proposed a number of changes to the Nutrition Facts Panel on packaged food, including the partition of information on sugar into total "Sugars" with a separate category termed "Added Sugars." In proposing this change, FDA relied on authority provided in the Food Drug and Cosmetic Act that allows changes to the Nutrition Facts Panel to help consumers "maintain healthy dietary practices." According to FDA, including Added Sugars will "help consumers understand how much sugar is naturally occurring and how much has been added to the product" with the premise that added sugars "provide no additional nutrient value…"

The Added Sugars proposal raises a number of questions and concerns. For one, as proposed, the category of Added Sugars includes any type or amount of sugar added to foods during processing or preparation, failing to distinguish between the addition of raw untreated sugar products, common refined sugar, naturally-occurring sugars from whole food sources such as fruit juice, and modern, highly synthesized ingredients such as high fructose corn syrup. To the FDA, the fact that sugar is added appears more important than what is actually being added. Indeed, the FDA acknowledges its rationale for making added sugars a mandatory declaration "is different from our rationale to support other mandatory nutrients to date," and that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.

It is also not clear whether information on Added Sugars is truly helpful to consumers, or just likely to cause confusion. One study, published in August 2014, tested consumer perceptions of the relationship between total carbohydrates, sugars, and added sugars, and investigated how consumers use the Nutrition Facts panel to make purchasing decisions. Shown different versions of the Nutrition Facts panel, 92 percent of consumers were able to correctly determine how much sugar was contained in the product when using the current Nutrition Facts panel, while only 55 percent and 66 percent of consumers were respectively able to determine total sugar content when shown a panel with Added Sugars information. According to researchers: "34 percent believe [Added Sugars] simply means more sugar has been added to the products, 28 percent think the line distinguishes between added sugars and sugars that are naturally occurring in the other product ingredients, [and] about one in five (19 percent) just don't know what it means."

From a litigation perspective, the most troubling aspect of the Added Sugars panel is the potential for this new labeling requirement to provide fodder for food labeling lawsuits. Given the lack of reliable evidence on the health effects of Added Sugars as opposed to total sugar intake, it is unsurprising that the FDA has thus far declined to provide guidance to food manufacturers on the proper protocol for measuring and establishing which sugars are "added." What is more, FDA acknowledges: "[T]here are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food."

In lieu of reliable analytical methods for measuring added sugar content, the FDA proposes new mandatory record-keeping procedures that would allow regulators to verify that the Added Sugar content reported on the label matches up to the sugars added according to a food manufacturer's production protocols. FDA could, in theory, take action against a food manufacturer who fails to maintain adequate records, even if there is no affirmative evidence that the product in question was mislabeled. Such an approach, in turn, leaves plaintiffs free to file suit by arguing that the manufacturer misled the public in reporting a specific Added Sugar content, when in fact the manufacturer could not verify that the reported amount was accurate. Under this approach, FDA's record-keeping policies potentially turn manufacturers into defendants.

The Added Sugars declaration could also lead to litigation against manufacturers of food products that contain multiple sweetening agents, particularly if naturally-occurring sweeteners such as fructose are involved. While the FDA notes that certain products such as soda will contain only added sugars, its simplistic Added Sugars model makes no mention of how to sort between multiple ingredients that all contain some type of sugar.

> If consumers do not generate demand for sodium reduction in their purchasing preferences—which has the effect of punishing manufacturers who voluntarily reduce sodium in their products—what reason is there for a manufacturer to make a meaningful reduction short of an FDA mandate?

Consider a hypothetical juice product made from 90 percent grape juice and 10 percent pineapple juice. The manufacturer, not unreasonably, considers sugar in the grape juice inherent in the production process and sugar from the pineapple juice to be Added Sugar, and the labeling reflects this view. In a case like this, however, the FDA provides no standards as to how the manufacturer should determine which are the inherent sugars and which are the Added Sugars. A skilled plaintiff attorney is free to file suit claiming that the product is mislabeled, either

on a theory that the inherent sugars should actually be reported as Added Sugars, and vice versa, or that all of the sugars in this product should be reported as Added Sugars.

This problem is even more pronounced if one considers another hypothetical juice product made from equal parts of 10 different types of juices, similar to a number of currently popular brands. Which of the 10 potential sources of sugar are Added Sugars? Likewise, imagine a cereal in which sucrose is added to the cereal flakes, and then later in the production process apple juice is added for flavor. Is the fructose from the apple juice an Added Sugar, or is it only the sucrose? If the manufacturer fails to include the fructose as an Added Sugar, have they mislabeled its product? The only certainty is that the FDA has thus far given no indication to manufacturers how to handle this issue, leaving manufacturers to guess on the right approach and plaintiffs free to argue that a different approach should have been followed.

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Salt: Lower Levels or Else?

In June 2014, a few months after FDA presented its Added Sugars proposal, the Administration announced its intent to issue voluntary guidelines for food producers to reduce sodium levels. While FDA has not put forward any timeline for these guidelines to be released, the public was told to expect them "relatively soon."

The impending new guidelines raise a number of potential issues for food manufacturers. First and foremost is the question of whether a manufacturer should try to comply with the guidelines, given that they are not mandatory. While reducing sodium content would likely enamor a manufacturer to the public community and regulators, a significant drawback to voluntary sodium reduction is the potential to fall behind in the marketplace. Sodium plays a key function in many foods, improving texture, color, and controlling for microbes. Maintaining those qualities while reducing sodium is a significant obstacle for a manufacturer, and consumer reaction to reduced sodium levels is often negative. For example, a 2010 initiative by Campbell's Soup to reduce sodium content was well-received by public health advocates but fared poorly with consumers. In 2011, Campbell's added the salt back.

If consumers do not generate demand for sodium reduction in their purchasing preferences—which has the effect of punishing manufacturers who voluntarily reduce sodium in their products—what reason is there for a manufacturer to make a meaningful reduction short of an FDA mandate? One significant motivation for voluntary compliance is the potential that industry-wide refusal to comply with the new guidelines—or the refusal to at least make a serious attempt to comply—could give FDA no option short of issuing mandatory sodium reduction regulations. It seems apparent from both the Added Sugars initiative and the forthcoming sodium reduction guidelines that the current environment at FDA is one in which food manufacturers will not be granted the benefit of the doubt, and initiatives favored by "consumer advocates" may be adopted by FDA even if the science behind them is not yet well-established. Given this regulatory climate, industry may be wise to avoid putting FDA into a position where it is left with no choice but to mandate sodium reduction.

It is also worth noting that the FDA has more than one way to force manufacturers to lower sodium levels. While a direct mandate identifying maximum allowable sodium content is the most obvious course, FDA could also pursue indirect methods, such as modifying or eliminating sodium's GRAS status. When FDA first formulated the GRAS list in 1959, it did not formally list salt as a GRAS ingredient. The reason was that FDA judged it "impracticable" to formally list all GRAS substances, and named salt, along with pepper, vinegar, and baking powder as examples of "common food ingredients" that were considered safe and presumed to be GRAS. From a regulator's perspective, then, the GRAS status of sodium has always been presumed, never scientifically established. Indeed, a 1979, a report by the Select Committee on GRAS Substances concluded that: "The evidence on sodium chloride is insufficient to determine

that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced." The framework exists, then, for FDA to undertake a review of sodium's GRAS status, and eliminate that status if so inclined. While stripping sodium of its GRAS status represents something of a "nuclear option" for FDA, it is nonetheless an option available to the Administration to reduce sodium levels in processed foods. Accordingly, some amount of cooperation with the FDA on sodium reduction would seem an ideal path for food manufacturers rather than risking the imposition of new regulations entirely from above.

Working with FDA could lead to novel approaches that benefit all parties. From a health and regulatory perspective, one concern for both sugar and salt are the levels of each ingredient found in foods not typically associated with them. One potential way for industry to address this concern while protecting its own interest is to focus regulators on a narrower field of products where sodium reduction would be most beneficial. Potato chips, for example, are an obvious high sodium food where the salty taste is at the heart of consumer appeal. Mandating reduced sodium levels that would apply to products like this is a questionable use of limited resources both among regulators and industry. Accordingly, the two sides could work together to identify this and other obvious high-sodium foods for exemption to sodium reduction standards, perhaps including notice or warning that the sodium level in that product exceeds the amount recommended in the government's Dietary Guidelines.

There are also commercial advantages to treating the voluntary sodium reduction guidelines as if they presage a mandate. Manufacturers who investigate lower sodium alternatives to their current products will have the advantage of using this time to develop products that consumers will find more palatable despite their lower sodium content. When lower sodium levels are mandated, a manufacturer who is prepared could enjoy considerable advantage over the competition if its low-sodium lines are store-ready while competitors are still working to comply with the new standards.

FDA's Isolated Approach

One thing that should not be lost in focusing on the FDA's sugar and salt initiatives is the fundamental question of whether an ingredient-by-ingredient approach to food regulation is most beneficial for consumers. A significant amount of research suggests that high blood pressure, typically associated with Americans' high sodium diet, is more a result of the overall low potassium intake in the U.S. In other words, the problem is not that Americans eat too much salt, but that they eat too few fruits and vegetables and other foods high in potassium. This may explain why, on average, people in countries such as Italy experience fewer cardiovascular problems than Americans do, even though its average salt intake is significantly higher than in the U.S. It also highlights the inherent limitations of regulating ingredients in isolation, and ignoring the potential that health effects associated with specific ingredients may also depend on the balance of those ingredients against other substances in the human body.

Political realities, and public relations, may make it easy to pursue regulation of certain ingredients and industries. But if the FDA is truly concerned with promoting a "balanced" diet, it should remember that balancing involves evaluating all of the variables against one another simultaneously. Picking at ingredients one-by-one without keeping the entire system in mind may ultimately increase the risk that consumers will develop the poor health conditions that FDA is attempting to curtail.

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Rethinking the FDA's Food/ Supplement Framework

This article originally appeared in the Food and Drug Institute's Policy Forum on April 2, 2014.

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In January 2014, the Food and Drug Administration (FDA) released a new guidance for industry titled: "Distinguishing Liquid Dietary Supplements from Beverages." Concerned about an "increase in the marketing of liquid products with a wide array of ingredients and intended uses," the FDA issued this new guidance to "help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage."1 Underpinning this concern is a growing sensitivity by the FDA that a significant number of liquid products may be misbranded as dietary supplements due to the fact that their labeling and promotional materials make representations that are more consistent with traditional beverages.

The new guidelines are a curious form of "guidance," setting forth an eight factor test meant to answer the fundamental question of whether Product X is a supplement or a traditional beverage but never articulating a definitive basis from which a manufacturer could make such a determination. For example, in their attempt to identify the most important factors in determining a product's proper category, the guidelines pay little attention to the actual composition of the product, with the overwhelming focus on how a product is marketed, labeled, or positioned in the marketplace. Indeed, a liquid product's composition — what the product is actually made of — is just one among eight purportedly equal factors in the FDA's test, with all of the remaining factors focused on claims made about the product or the manner in which it is sold. Against this background, the time is right to question whether the FDA's current distinction between foods and dietary supplements continues to best serve both public and industry interests.

The FDA should seriously consider eliminating food/ supplement distinction all together, and developing a comprehensive set of regulations that will apply uniformly to products now considered either foods or supplements. For example, rather than maintaining the distinction between "Nutrition Facts" and "Supplement Facts" in product labeling, it could be more helpful to develop a single ingredient disclosure scheme that would cover all products now considered either foods or supplements.

Policy Recommendations

If eliminating the food/supplement distinction is too radical a change, the FDA should at a minimum develop guidance that establishes a truly meaningful distinction between foods and supplements. Any such guidance would need to do at least the following:

- Take an overall approach that if foods and supplements are to be the subject of two different sets of regulations, the distinction between the two categories should be fundamental. In other words, the goal should be to properly define what is a food and what is a supplement, and avoid defining the two types of products solely in relation to each other.
- Place significant weight on concrete factors such as the composition of a product or recommended daily intake and require the "Fact" panels for foods and supplements to provide the same categories of information so that consumers can easily determine the differences between drinks that are "foods" compared to those that are "supplements."
- Reduce emphasis on elastic factors such as marketing strategy or product placement.
- Provide clear guidance on how any factors are to be weighed against one another.

The clarity of either eliminating the food/supplement distinction, or truly making that distinction apparent, can only benefit everyone involved — manufacturers, consumer, and regulators.

II. Foods vs. Supplements: The Basic Distinction

As might be expected, the Food Drug and Cosmetic Act (FDCA) definitions of food and dietary supplement are vague and not particularly useful. Beverages are considered traditional foods under the FDCA, which is to say that a product is a beverage if it is "used for food or drink for man or other animals."[2] By contrast, a dietary supplement, in addition to containing one or more of certain listed ingredients such as amino acids, vitamins, herbs, or other "dietary substance for use by man to supplement diet," is defined in the negative; as a product "not represented for use as a conventional food or as a sole item of a meal or the diet."[3]

The broad principle to take from these definitions, which can be seen throughout the new guidelines and the FDA's overall consideration of the issue, is that beverages serve the basic purposes of the human diet, consumed for nutrition, hydration, or taste. Supplements, on the other hand, are a compliment to the nutrition obtained from consuming foods and beverages. To navigate this divide, a manufacturer trying to decide if a product is a food or supplement in the eyes of the FDA should begin by asking: "Why is the consumer supposed to eat or drink this product?" The answer to this question is perhaps the most significant factor in determining the proper classification for any product under the FDA's guidelines.

III. Why the Food/Supplement Distinction Matters

While the FDA treats both foods and supplements similarly in some respects — neither must undergo safety or efficacy testing as drugs do — the distinction between the two yields several significant differences in how they are treated under the law and FDA regulations. While neither foods nor supplements may claim to treat, diagnose, or cure a disease, supplements must include a disclaimer on their label saying exactly that.4 This indicates an apparent belief by the FDA that supplements are perceived by consumers as more "drug like", a view that is supported by a provision of the FDCA that forbids marketing a dietary supplement when the same substance has been the subject of a substantial clinical development program aimed at drug approval.5 This provision is designed to keep failed drugs from reaching the market, re-imagined as dietary supplements, while no similar provision applies to foods or beverages. Moreover, like drug makers, manufacturers of supplements are required to report adverse events associated with their products to the FDA.[6]

Supplements and foods are subject to different labeling requirements. Although supplements must list dietary ingredients in a "Supplement Facts" panel without any indication of the Recommended Daily Intake, dietary ingredients cannot be included in the "Nutrition Facts" panel required for food and beverage products. Similarly, while the Nutrition Facts panel requires that certain nutrients not present in a particular product be listed with a zero value, nutrients not contained in a dietary supplement may not be included in a Supplement Facts panel, even with a zero value.[7]

Supplements and foods are also treated differently under the FDA's Generally Recognized as Safe (GRAS) criteria.

Food additives require premarket approval by the FDA unless they qualify as GRAS.8 Otherwise, the FDA considers the food adulterated. While the ingredients contained in dietary supplements similarly cannot adulterate a product, they do not have to be GRAS for their intended use in a supplement.9 This difference can have considerable impact on the allowable composition of foods and supplements, with respect to additives such as caffeine. Caffeine is GRAS up to .02% of a beverage, which effectively caps the amount of caffeine that can be added to a beverage.[10] However, if a liquid product qualifies as a supplement, there is no .02% GRAS restriction, meaning that a liquid supplement — such as an energy drink — is not subject to any limitation on its caffeine content. This particular aspect of the food/supplement distinction has come to the forefront over the last year as energy drinks specifically have been the subject of regulatory scrutiny and even litigation over their caffeine content. It is no accident, therefore, that on the same day that the FDA issued the new guidelines on distinguishing supplements from beverages, it issued a separate guidance to cover dietary ingredients added to traditional foods, stating: "Substances that have been present in the food supply for many years are now being added to beverages and other conventional foods in excess of their traditional use levels. This trend raises questions regarding whether these new uses are unapproved food additive uses."[11]

> The new guidelines are a curious form of "guidance," setting forth an eight factor test meant to answer the fundamental question of whether Product X is a supplement or a traditional beverage but never articulating a definitive basis from which a manufacturer could make such a determination.

Clearly, then, there is real significance to a manufacturer in terms of how they may formulate, market, or label a product based on whether it qualifies as a food or supplement for regulatory purposes. Following the latest guidance and making sure that a product properly fits into the category where the manufacturer seeks to place it, is of great importance — otherwise there is a real risk that the FDA will consider the product misbranded.

IV. It is Not What You Make But How You Sell It

According to the FDA's recent guidelines, there are eight factors to consider in evaluating whether a liquid product can properly claim to be a beverage or a dietary supplement. Whether a product is a supplement or a beverage depends on the overall balance of the factors, but the guidelines themselves do not provide any real sense of how these factors should be balanced or perhaps more important, would be interpreted by the FDA or a court. Is it as simple as counting how many favor a beverage versus how many favor a supplement? Or is it really a qualitative analysis, in which the outcome of a minority of critical factors could tip the balance one way or the other? No reliable answer is apparent in the latest Guidance, but an analysis of each of the factors individually is an informative approach to discerning what the FDA considers vital in answering the food or supplement question.

A. Labeling and Advertising Claims

The key inquiry for this factor, consistent with the overall food/supplement distinction, is whether the product is advertised as providing some form of nutrition on its own, or whether it merely claims to enhance diet. A liquid product that claims to "refresh" or rehydrate" would probably qualify as a food even if it had no other nutritional value because rehydration is the primary purpose of most beverages. The import of claims in deciding where a product falls may turn on comparison to other products. For example, a supplement that was advertised as tasting better than Pepsi or Coke would likely be considered a beverage under this factor, by virtue of the comparison to well-established beverages. Dispositive claims can also include visuals, such as showing a supplement being poured over a green salad as a claim that it is intended for use as salad dressing, a food.

B. Representations Outside of Labeling and Advertising

This factor deals with claims made about a product in publicly available documents, such as filings with the Patent and Trademark Office or the Securities and Exchange Commission. These claims are likely far less important in the total calculus of factors than advertising claims directed at a broader audience. Still, if a manufacturer marketed its

product as a beverage while holding a patent on it as a novel nutritional supplement, that would be relevant to the ultimate determination of how the product would be classified by the FDA.

C. Product Name

Perhaps the factor most easily used to steer a product toward one classification or the other, the FDA attaches great significance to a liquid product's name in determining how that product should be regulated. According to the guidelines: "In some instances, the mere use of such a term in a product name or brand name may be sufficient to establish that the product is represented for use as a conventional food."[12] The guidelines also make clear the FDA view that product or brand names which use conventional food terms such as "beverage" "drink" "water" or "soda" represent the product as a beverage. Presumably, this has considerable implications for the ultimate classification of the aforementioned energy drinks, a number of which use the word "drink" on the front of the can, even though they are marketed as supplements. This would appear inconsistent with the FDA view that conventional food terms such as "drink" strongly suggest that the product is a beverage.

D. Packaging

Undeniably, packaging can convey a message about how a product is intended to be used. For the FDA, relevant factors include size, shape, color, the volume of liquid it holds, and whether it is re-sealable or designed such that it can only be consumed as a single serving. Similarity to other types of packaging is also important. For example despite the use of the word "supplement" in its name, the guidelines suggest that a liquid product packaged "in a red, 12 ounce pop-top aluminum can bearing a silver stripe with the name 'Cola Supplement' printed on the can" is likely a beverage.[13]

E. Serving Size and Recommended Daily Intake

This factor relies on survey data indicating that the average American adult consumes 1.2 liters of fluids other than water in a day for the purpose of nutrition or hydration,. Liquid products that suggest that they are intended to be consumed in amounts that approach that assumed daily intake are presenting themselves as beverages. The emphasis here is that beverages are products intended to wholly replace the source of that 1.2 liters such that a product whose packaging states "Drink up to three 16-ounce bottles per day" is classified as a beverage. Conversely, liquids that suggest consumption at far lower levels than 1.2 liters daily present themselves as supplements. Consider how many "energy shots" a consumer would need to drink in order to reach 1.2 liters in a day.

> The goal should be to properly define what is a food and what is a supplement, and avoid defining the two types of products solely in relation to each other.

F. Recommendations and Directions for Use

Dietary supplements, to risk oversimplification, are intended to supplement diet. Ideally, the directions for use that accompany a supplement would state that they should be used in conjunction with conventional food or drink. In contrast, beverages are intended to quench thirst or provide a source of fluids (water) or provide nutritive value (orange juice/milk) or simply just taste good (hot chocolate). Recommendations for use that appeal to one of these factors make it more likely that a product is a beverage.

G. Marketing Practices

Encompassing more than just advertising claims, the focus with this factor is on other ways of positioning a product in the marketplace, such as sponsorships and product placement. It also includes meta-tagging, where a supplement, for example, appears in internet search results for beverages. In describing how marketing practices can affect the classification of a product as a beverage or a supplement, the FDA appears to place a strong emphasis on whether and how the product is compared to "traditional" forms of beverages or supplements in the producer's marketing efforts. Marketing practices that are traditionally associated with products in one category can help determine whether a new product that follows those traditional practices is a food or supplement. Yet, this is potentially one of the most confounding factors discussed in the FDA guidelines.

Take the case of a liquid designed to replace orange juice. If marketed as a more efficient way of obtaining Vitamin

C and other nutrients found in orange juice, that would tend to suggest that the FDA considers that product a supplement. If marketing for that product includes mention of rehydration or thirst quenching, however, the same product might be considered a beverage. If the producer of a new liquid supplement began to post window and store displays and install branded cooler units in stores that sold its product, similar to those offered by soft drink companies, it is very possible that adopting the marketing practices of those companies could be taken as a suggestion that the product is a beverage and not a supplement. Even a decision as to where in the store the product is intended to be available, could, under this factor, be dispositive of whether the FDA would view this product as being marketed as a beverage as opposed to a dietary supplement.

H. Composition

The lone factor that deals with the actual make-up of the product. The guidelines concede the complexity involved with this factor, because there are undeniable areas of overlap in terms of the ingredients in foods and supplements. However, the FDA maintains that the overlap "is not intended to be total…[it] would strain common sense to authoriz[e] the creation of a dietary supplement whenever any dietary ingredient is added to a conventional food."[14]

It appears that the FDA's concern here is that, without considering composition, manufacturers might attempt to evade GRAS requirements for foods simply by adding an inconsequential dietary ingredient to a product that would otherwise be classified as a traditional food or beverage. Likewise, they are mindful that certain dietary ingredients that may lawfully be added to supplements may not be lawfully added to foods. For example, those that are not in conformity with food or color additive regulations.

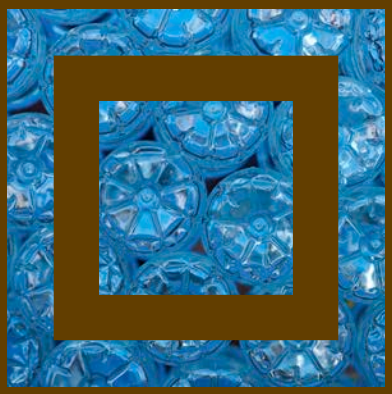
As is the case with most of the factors discussed in the FDA Guidance, the composition factor leaves manufacturers, consumers and regulators with surprisingly little clarity as to how it is to be integrated with the other seven factors to determine the appropriate classification of a liquid product as a beverage or a diet supplement, especially when those other seven factors deal with seemingly intangible interpretations of marketing, packaging, or advertising practices. What is the concentration of dietary ingredients in the overall composition for a product that will qualify that product as a supplement? Is the relative concentration of dietary ingredients in the overall composition of the product more or less important than the manner in which dietary ingredients are emphasized in packaging or marketing? If how a product is marketed or advertised outweighs the product's actual composition, why consider composition at all? Are there products that would qualify as foods or supplements no matter what their packaging says or how the product is marketed and promoted? Far more questions than answers present themselves when this factor is integrated into the test.

V. Guidance or a Recipe for Confusion?

One of the most striking features of the FDA's approach to this issue, as exemplified by the "guidance" discussed above, is how elastic the guidelines appear to be, especially when one tries to integrate them in an attempt to determine whether a particular liquid will be deemed by the FDA and consumers as a beverage or a supplement. Many of the factors identified by the FDA involve factual scenarios that can change quickly, particularly given the fact that the interpretation of many factors will be governed by how the product under consideration compares to other "traditional" products in the context of its promotion, package form, size and labeling, and even its placement in a particular store. With such an emphasis on marketing factors, it is not an exaggeration to say that, under the FDA's stated approach, a beverage is one advertising claim or store shelf away from becoming a supplement, and vice versa.

The absence of a meaningfully definitive set of guidelines on the distinction between beverages and supplements also limits the utility of seeking advice from the FDA prior to introducing a new product, new packaging, or prior to undertaking new marketing initiatives. Even if a producer "pre-clears" a product or a marketing campaign with the FDA, these guidelines make it difficult if not impossible to determine how a business driven change with respect to any of the factors might tip the scales of an FDA analysis in a different direction such that any comfort derived from the FDA's prior advice would be lost.

Moreover, given the current litigation environment involving food and supplement products in which a single word or phrase can give rise to class action claims that a product is being "falsely" marketed or sold, the current FDA guidelines will provide little guidance to courts in



The ambiguity and uncertainty inherent in the FDA's recent Guidance requires one to question whether there is any value at all to making a regulatory distinction between "foods" and "dietary supplements."

determining the merits of those claims, and will likely result in conflicting rulings based on varying interpretations of the FDA's stated criteria.

If "foods" can become "supplements" based on how they are packaged, labeled, marketed or placed within a store, as opposed to the composition and relative concentration of their ingredients, any benefit to maintaining food/supplement "distinction" becomes highly questionable. Indeed, if the actual content of a product is less important to the distinction between foods and supplements than the manner in which a product is sold, the distinction is more ephemeral than it would appear, especially in the context of informing consumers.

The FDA recognizes the need to provide clear and informative information about food products as demonstrated by the recently revised rules for the information to be disclosed in the "Nutrition

Facts" panel, yet there is a different set of disclosure requirements regarding the labeling for supplements. Given the plethora of ingredients now used in both food and supplement products and the blurred lines regarding a consumer's reasons for choosing a particular food or supplement product, it seems that the best approach is for the nature and extent of ingredient disclosures to be the same for all products that fall within those two categories.

While there are undoubtedly some nutrition industry manufacturers who see the mutability of the FDA standards as providing flexibility in permitting them to classify their products based upon how they choose to advertise and promote them, the uncertainty inherent in the FDA guidelines also carries no small share of risk. Every misapplication of the food/supplement distinction yields a misbranded product, and with that not only FDA action, but also a potential class action lawsuit.

VI. It Is Time to Eliminate the Food/Supplement Distinction

The ambiguity and uncertainty inherent in the FDA's recent Guidance requires one to question whether there is any value at all to making a regulatory distinction between "foods" and "dietary supplements." A single uniform standard will give consumers clarity with respect to the nutritional content of what they purchase or consume, and will provide suppliers with a clear set of guidelines for their products that are based on content as opposed to intangible subjective interpretation of their marketing intent.

In the alternative, if the FDA continues to insist on maintaining a distinction between foods and supplements, it should establish a fundamental distinction that enables consumers and manufacturers to discern a meaningful difference between products in these categories -- based on the ingredients they contain and their relative nutritional content as opposed to marketing techniques and comparison to other products. At a minimum, there should be uniformity with respect to ingredient and nutrition labeling so that consumers can make informed decisions.

Without eliminating what is likely an unnecessary distinction between foods and supplement or providing a concrete basis to define those products and maintain a distinction, the current Guidance is likely to engender more confusion for consumers and manufacturers than it purports to resolve.

1. FDA Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages, p. 1-2 (January 2014).
2. 21 U.S.C. §321(f)(1).
3. 21 U.S.C. §321(ff).
4. 21 U.S.C. 343(r)(1)(B).
5. 21 U.S.C. §321(ff)(3)(b)(2).
6. 21 U.S.C. §379(aa)(b)(1).
7. 21 CFR 101.36(b)(2)(i)-(3); 21 CFR 101.4(h), 21 CFR 101.36(d)-(d)(1); 21 CFR 101.9.
8. 21 U.S.C. §348; 21 CFR 170.30.
9. 21 U.S.C. §321(f).
10. 21CFR182.1180.
11. FDA Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements, p. 1-2 (January 2014).
12. Id. at p. 3.
13. Id. at p. 3.
14. Id. at p. 4.

Energy Drink Companies May Find State AG Suits Hard To Swallow

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Long in the crosshairs of Congress and personal injury attorneys, the makers of energy drinks may now face a new type of challenge to their products in the wake of recent lawsuits filed by the attorneys general of three states. Previous litigation involving energy drinks focused on the alleged health risks of these products or claims that they are improperly marketed to children, often based on allegations that these products contained excessive amounts of caffeine. These new lawsuits, however, make use of state false advertising statutes to attack fundamental claims regarding how one specific energy drink works and the benefit it provides to the consumer.

Brought by the attorneys general of Oregon, Washington and Vermont in July 2014, the substantially similar complaints allege that Living Essentials LLC and its parent company Innovation Ventures LLC, makers of the popular drink 5-Hour Energy, engaged in a number of practices that constitute false and deceptive advertising under applicable state laws. Specifically, the suits allege that the "energy boost" gained from drinking 5-Hour Energy comes exclusively from its caffeine content, and attack claims that the product's proprietary formula of vitamins and other non-caffeine ingredients produce the enhanced energy effect. Likewise, the attorneys general allege there is no credible basis for the claim that 5-Hour Energy users do not experience a "crash" when the product wears off, and that the defendants falsely misled consumers into believing that 5-Hour Energy was recommended by doctors. The plaintiffs seek civil penalties, disgorgement and injunctive relief.

No doubt, the decision to pursue these cases is driven, at least in part, by the success of energy drinks over the last decade. While sales of traditional drinks, such as soda, have declined in recent years, energy drinks have surged in popularity, creating the potential for significant recoveries against the companies that make and market them. At the same time, criticism of the industry by

members of Congress and federal regulators, including a 2013 report from the US Department of Health and Human Services that referred to energy drinks as a "rising public health problem," lends additional pressure that can be used by the attorneys general to try and force settlements.

> ...Any member of the industry would be well-served to review their past advertising claims and assess any statements that could potentially be challenged in future actions.

But the decision to proceed with the suits against 5-Hour Energy may also represent a new tactic built around depriving defendants of key defenses asserted in similar litigations in the past. Primary jurisdiction, for example, is a doctrine that allows a court to stay or dismiss a case pending the resolution of an issue within the special competence of an administrative agency. This defense has previously been used in cases like Aaronson v. Vital Pharmaceuticals, a 2010 decision by the US District Court for the Southern District of California that invoked primary jurisdiction to dismiss state law claims against a defendant accused of wrongly promoting the safety and health effects of its energy drink. Finding the plaintiff's claims to be based upon the contention that the product was not safe, the court in Aaronson stated that in order to evaluate those claims it would "likely need to evaluate conflicting studies" and determine whether the product "should be approved as safe." These issues, the court concluded, "are best suited for the [USFood and Drug Administration]."

In the same vein, because the 1990 Nutritional Labeling and Education Act expressly preempts states from directly or indirectly establishing food and beverage labeling requirements that are "not identical" to the FDA requirements for ingredients, nutrition and health-related claims, defendants in similar lawsuits have also asserted preemption as a defense. Preemption has been particularly successful in dealing with state law claims that would have required packaging include statements about ingredients that were different from the statements mandated under the NLEA.

What is novel about the recent attorney general actions against 5-Hour Energy is that they appear to be an end-run around primary jurisdiction and preemption, because they do not address the product's labeling or nutritional disclosures as a primary focus. Instead, the three complaints take aim at rather straightforward claims in print and television marketing regarding how 5-Hour Energy works, what results users can expect and the opinion of the medical community regarding the product. By taking this approach, the attorneys general are likely attempting to avoid the complications of challenging a product's labeling or overall safety, potentially drawing force away from the jurisdictional defenses that defendants have favored in the past.

Grounded in state law and addressing advertising claims that must be addressed on the merits, these new lawsuits take an approach that places defendants in a difficult position. This is particularly true with respect to the claims regarding the source of the "energy boost" provided by 5-Hour Energy. The attorneys general claim that it is caffeine—and caffeine alone—that produces this effect. However, in order to refute this claim, and prove their advertising claims accurate, the defendants may need to disclose the proprietary formula which gives them an advantage in the marketplace. For the makers of 5-Hour Energy, then, its most effective defense may come with the risk of increased competition from copycat products. With such an option likely distasteful to the defendants, the attorneys general could hold considerable leverage in negotiating settlement terms.

The most significant worry for energy drink makers, however, is that the 5-Hour Energy cases will turn into a blueprint for nationwide litigation by state attorneys general. Indeed, the cases filed last month may just be the vanguard against that particular product, as 33 states in total conducted investigations into the marketing claims challenged by the suits from Oregon, Vermont and Washington. If those cases are successful, they may provide a strategy to follow against the industry collectively.

One potential effect may be to revive seemingly stalled investigations. In July 2012, New York Attorney General Eric Schneiderman issued subpoenas to three energy drink makers, including Living Essentials. The focus at that time was whether any of these companies violated federal law by marketing their products as supplements rather than foods, but state authorities also expressed concern about whether

those products properly disclosed the caffeine content from all ingredients. No lawsuit resulted; and, had the attorney general brought a case targeting labeling disclosures and made the food vs. supplement distinction a key issue, which was recently the subject of a January 2014 FDA guidance document for industry, the defendants could have been expected to offer vigorous jurisdictional defenses. Now, the state attorneys general appear to believe that their new approaching these recent cases may offer a way forward that avoids thorny intersections between state and federal law altogether.

Makers of energy drinks would be wise to carefully monitor the progress of the three cases filed in July, most especially to see whether the scope of the litigation against 5-Hour Energy expands to additional states. In the meantime, any member of the industry would be well-served to review their past advertising claims and assess any statements that could potentially be challenged in future actions. This should include an assessment of what sufficient, scientifically rigorous data is available to back certain claims, and efforts to supplement the field of data if necessary. Consultation with experienced counsel should be a key feature of this process.

In all likelihood, now that the first shots have been fired, the momentum of the 5-Hour Energy cases will continue in any state that has a false advertising statute sufficient to support the claims already made in Oregon, Vermont and Washington. In turn, state attorneys general are likely to focus on other energy drink makers, closely scrutinizing their past advertising claims to find grounds for additional suits. While the industry cannot halt state officials from undertaking this process, manufacturers of energy drinks can take steps to prepare themselves to defend their products and potentially dissuade state attorneys general from bringing questionable cases against well-prepared adversaries ready to mount a vigorous defense.

About Kaye Scholer's Food, Beverage & Supplement Group:

Few industries have undergone as rapid a transition as the food, beverage and supplements industry has in the past 20 years. The extraordinary growth of the world's interconnected food markets, combined with the passage of the 2011 Food Safety Modernization Act (FSMA), has created something of a legal maelstrom for the food and beverage industry. As a result, food companies are facing new, more challenging legal issues when it comes to food safety, labeling, marketing and advertising, storage and distribution of fresh, frozen and pre-packaged foods and beverages. Kaye Scholer's Food, Beverage & Supplement Group offers a multidisciplinary approach to respond to, resolve or successfully litigate matters that threaten or challenge growers, manufacturers, distributors and sellers of food, beverage and supplement products.

Experience Matters

Drawing on more than 50 years of experience representing consumer products and life sciences companies in complex disputes and government investigations, we have a proven track record representing some of the world's biggest and best known brands, including The Hershey Company, Tropicana Products, Chiquita Brands, DuPont, Pfizer and Novartis, to name just a few. We have particular experience coordinating and litigating multi-district and multi-state class and mass actions, regularly serving as national counsel in class and mass action matters, including overseeing case management for all of a client's outside law firms involved in the defense of a particular product. We also have significant experience protecting food brands' trademark rights-including serving as Hershey's outside IP counsel for more than a decade—and defending them in false advertising allegations. We also have represented food and beverage companies in corporate, bankruptcy, antitrust, national security and tax matters.

We Know the Science

A successfully defense starts with reviewing how the scientific claims being made regarding the health benefits of your product or ingredients are supported by credible and reliable science, and that the science has been fairly applied. This is a particular strength of Kaye Scholer, as we have been extremely successful in refuting allegations filed against our pharmaceutical clients by demonstrating how plaintiffs' scientific methodology is faulty. What's more, we can explain the science behind your product in a way that makes sense to both judges and juries alike. Many of our lawyers also have degrees and/or strong backgrounds in the sciences, and we also have on-staff scientific advisors, as well as consumer perception researchers. Because of our ability to strip away at the scientific jargon and truly examine the methodology and research employed by opposing counsel, we are highly adept at using Daubert and scientific evidence gathering to help get cases dismissed early in the process.

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Kaye Scholer at a Glance

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