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Rethinking the FDA's Food/Supplement Framework

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I. INTRODUCTION

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]

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.

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 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.

ENDNOTES

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.

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