UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAUL GEORGE, individually and on behalf of all others similarly situated in Missouri, Plaintiff, vs. BLUE DIAMOND GROWERS, Defendant.	Case No. 4:15-cv-00962-CEJ

PLAINTIFF'S MOTION TO RE-OPEN CASE AND TO LIFT THE STAY

Plaintiff Paul George ("Plaintiff") submits this Motion to Re-open Plaintiff's case and to Lift the Stay in accordance with this Court's Orders, dated April 14, 2016 (Doc. 30) and April 21, 2016 (Doc. 31), which directed that this case remain stayed (Doc. 30) and administratively closed (Doc. 31) pending the U.S. Food and Drug Administration's regulatory process regarding the terms "evaporated cane juice" ("ECJ") and "natural." A lift of the stay and re-opening of the case is appropriate because (1) the FDA has provided guidance regarding the term ECJ, which directly impacts this case; and (2) in opening a comment period for the term "natural," the FDA has not indicated when, if at all, it will issue guidance regarding the use of the term "natural." For 23 years the FDA has considered the term "natural" to mean that nothing artificial or synthetic is added to a food. And, it is likely that the FDA will not provide additional guidance regarding the term "natural" for several years, if at all. It would prejudice this case to continue to wait for such guidance, which may not be forthcoming.

INTRODUCTION AND PROCEDURAL BACKGROUND

On April 14, 2016, this Court ordered that the case be stayed pending the FDA's ongoing examination of the use of the terms ECJ and "natural." (Order, Doc. 30, April 14, 2016). In its April 21, 2016, Order, this Court administratively closed the case and advised the parties to move to open the case when the FDA had issued additional guidance regarding the use of the terms ECJ and natural. On May 25, 2016, the FDA issued additional guidance regarding the use of the term ECJ. Between November 12, 2015, and May 10, 2016, the FDA accepted public comment on the use of the term "natural" in the labeling of human food products, but it is not clear that the FDA intends to offer additional guidance beyond the definition it adopted more than 20 years ago regarding the meaning or use of that term.

LEGAL STANDARD

When a court determines that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the action pending the agency's resolution of the question. *Jackson v. Swift Eckrich, Inc.*, 53 F.3d 1452, 1456 (8th Cir. 1995). The doctrine, and resulting stay, is to be "invoked sparingly, as it often results in added expense and delay." *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 477 (8th Cir. 1988) (internal quotations omitted). In granting a stay in this matter, this Court determined that it was appropriate to defer to the FDA's "'expert and specialized knowledge' in order to attain 'desirable uniformity'" with respect to the use of the terms ECJ and "natural." (Order, Doc. 30, p. 6.) Once the FDA exercises its expert and specialized knowledge, and issues guidance, a stay is no longer necessary. In addition, if it is unclear that the FDA will provide additional guidance, or that it may not do so for an extended period of time, a stay should be lifted. *See Lunde v. Helms*, 898 F.2d 1343, 1345 (8th Cir. 1990) (recognizing that an indefinite stay order can unreasonably delay a plaintiff's right to have his or her case heard and, therefore, is appealable).

ARGUMENT

I. The FDA Has Provided Clarification Regarding the Term ECJ and Has Not Indicated That it Intends to Provide Guidance Regarding the Term "Natural."

A. The FDA Determined that Use of the Term ECJ is False and Misleading.

With respect to ECJ, the FDA concluded its review process on May 25, 2016, and published a revised Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, Doc. No. FDA-2009-D-0430 ("2016 Final Guidance"). A true and correct copy of the 2016 Final Guidance is attached as Exhibit A. Because the Court stayed this case in part based on the FDA's statement that it intended to provide final guidance on the term ECJ by the end of 2016, and the FDA has now provided such guidance, the stay should be lifted. *See* Doc. 30, at p. 6.

Plaintiff's position regarding the FDA's policy on the use of the term ECJ proved to be correct—it is false and misleading. In the 2016 Final Guidance, the FDA reiterated its 16-year old policy that "the term 'evaporated cane juice' is not the common or usual name of any type of sweetener" and that the ingredient should "be declared on food labels as 'sugar,' preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses (e.g. 'cane sugar')." Ex. A at 4, 6. The FDA advised that "the term 'evaporated cane juice' describes neither the basic nature of the food nor its characterizing properties, and therefore does not comply with 21 CFR 102.5(a)," and stated that "the common or usual name for the ingredient currently labeled as 'evaporated cane juice" includes the term 'sugar' and does not include the term 'juice.'" *Id.* at 6-7. The 2016 Final Guidance reiterates what the FDA has been saying since 2000—use of the term ECJ is unlawful because it violates the "common or usual name" requirement in 21 C.F.R. § 101.4, and the requirement in 21 C.F.R. § 184.1854 that sucrose be referred to as "sugar" on food ingredient labels. In addition, ingredient lists identifying sweeteners derived from sugars such as ECJ are "false and misleading under section 403(a)(1) of the Federal Food Drug and Cosmetics Act (the "FDCA") (21 U.S.C. 343(A)(1)), because they do not accurately describe the basic nature of the food and its characterizing

properties (i.e., that the ingredients are sugars or syrups as required by 21 CFR 102.5)." Ex. A at 7.

Thus, because the FDA has issued its final guidance regarding the use of the term ECJ, Plaintiff respectfully requests that the Court lift the stay and re-open this case.

B. The FDA May Not Provide Additional Guidance Beyond the Existing Definition of "Natural," or May Not Provide It For Several Years.

The FDA's position on the term "natural" has not changed in 23 years, nor has the FDA indicated that it will change its position regarding the use of that term in products containing artificial, and non "natural," ingredients, such as Defendant's almond milk. The FDA's November, 2015 notice opening the comment period regarding the term "natural" does not indicate an intent to revisit its long-standing position that food with an "all natural" label may not include artificial or synthetic ingredients that one would not normally expect to be in the food. *See* 58 FR 2302, Jan. 6, 1993. Indeed, in opening the comment period, the FDA reiterated its "longstanding policy" that a product is not natural if it contains color, artificial flavors, or synthetic substances. *See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm,* attached hereto as Exhibit B.

Further, although the FDA sought public comment on the use of the term "natural," one of the issues on which it solicited comments was whether it is even appropriate for the FDA to define the term "natural." *Id.* The FDA has also previously admitted that, even if it opens an issue for public comment, there is no guarantee that it would "revoke, amend, or add to the current policy, or develop any definition at all." *See* Letter dated Jan. 26, 2014, from the FDA to three federal judges indicating that no guidance was forthcoming, attached hereto as Exhibit C. As such, guidance from the FDA on the issue is not imminent and, may, in fact, never be provided. At least one court has recognized that "[i]t would be impractical to stay or dismiss [a] case without any assurances that [the] FDA plans to define the term 'natural' as it pertains to food labeling." *Aguiar v. Merisant Co.*, No. 14–00670–RGK–AGR, 2014 WL 6492220, at *8 (C.D. Cal. Mar. 24, 2014).

Even if the FDA were to issue guidance, it has stated that, on average, it takes between 425 and 797 days to finalize guidance documents issued by the agency. *See FDA Withdraws 47 'Outdated' Guidance Documents*, http://www.raps.org/Regulatory-Focus/News/2015/05/05/22102/FDA-Withdraws-47-Outdated-Guidance-Documents/ (last visited Sept. 9, 2016) attached hereto as Exhibit D. Therefore, were the FDA to provide additional guidance, it is likely that it will not do so for several years. Such a delay would prejudice Plaintiff and putative class members, as well as cause additional expense and delay. Plaintiff has made claims for violations of the MMPA and for unjust enrichment based on Defendant's false and misleading product labels on its Almond Milk. If the stay is not lifted, consumers will continue to be misled by Defendant's deceptive labels; and Defendant will continue to be unjustly enriched.

Several courts have lifted similar stays based on the FDA's assertion that additional guidance regarding the use of the term "natural" may never come. *See Cox v. Gruma Corp.*, No. 12-CV-6502 (N.D. Cal. Jan. 10, 2014) (Order (Doc. 71) lifting stay and asking for briefing regarding the primary jurisdiction doctrine in light of the FDA's letter); *see also Barnes v. Campbell Soup Co.*, No. 12-CV-05185 (N.D. Cal. Jan. 24, 2014) (Order (Doc. 58) stating the same same). Because additional guidance regarding the use of the term "natural" may not be forthcoming, Plaintiff respectfully requests that this Court lift the stay. *See Aguiar*, 2014 WL 6492220, at *8.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that this Court re-open the case and lift the stay imposed by this Court's April 14, 2016 Order, and for such other relief as the Court may deem appropriate.

Dated: September 12, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2016, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which electronically delivered a copy of the same to all counsel of record.

/s/ Julie E. Piper-Kitchin_____

Ingredients Declared as Evaporated Cane Juice: Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling
Food Labeling and Standards Staff, HFS-820
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2371
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2009-D-0430 listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

May 2016

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Ingredients Declared as Evaporated Cane Juice: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to enhance consumers' ability to make informed choices among sweeteners by promoting accurate and consistent labeling. More specifically, this guidance is intended to advise the regulated industry of our view that the term "evaporated cane juice" is not the common or usual name of any type of sweetener and to assist manufacturers in appropriately labeling products that contain sweeteners derived from the fluid extract of sugar cane.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

In recent years the term "evaporated cane juice" has appeared as an ingredient on food labels, most commonly to declare the presence of sweeteners derived from the fluid extract of sugar cane. However, as discussed in detail in section III of this guidance document, FDA's view is that such sweeteners should not be declared on food labels as "evaporated cane juice" because that term does not accurately describe the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups) (Refs. 1, 2, 3). Moreover, the use of "juice" in the name of a product that is essentially sugar is confusingly similar to the more common use of the term "juice" -- "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree" (21 CFR 120.1(a)). Thus, the term "evaporated cane juice" is false or misleading because it suggests that the sweetener is "juice" or is made from "juice" and does not reveal that its basic nature and characterizing properties are those of a sugar.

As provided in 21 CFR 101.4(a)(1), "Ingredients required to be declared on the label or labeling of a food . . . shall be listed by common or usual name . . . ." The common or usual name for an

[1] This guidance has been prepared by the Food Labeling and Standards Staff in the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

ingredient is the name established by common usage or by regulation (21 CFR 102.5(d)). Each class or subclass of food is to be given a common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods. The common or usual name, which may be a coined term, must accurately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients; must be uniform among all identical or similar products; and may not be "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" (21 CFR 102.5(a)).

Sugar cane products exist in many different forms, ranging from raw sugars and syrups to refined sugar and molasses. These products are differentiated by their moisture, molasses, and sucrose content as well as by crystal size and any special treatments (e.g., treatment with sulfur).[2] Sugar cane products with common or usual names established by regulation are sugar (21 CFR 101.4(b)(20)) and cane sirup (alternatively spelled "syrup") (21 CFR 168.130). Several other sugar cane products have common or usual names established by common usage (e.g., molasses, brown sugar, turbinado sugar, muscovado sugar, and demerara sugar). For purposes of ingredient labeling, "sugar" is defined to mean sucrose obtained from sugar cane or sugar beets in accordance with 21 CFR 184.1854, the regulation affirming that sucrose is generally recognized as safe (GRAS) for use in food when used under specified conditions. The GRAS regulation describes sucrose as the substance "obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated" (21 CFR 184.1854(a)). To be GRAS for use in food, sucrose must be of a purity suitable for its intended use (21 CFR 184.1854(b)).

On October 7, 2009, FDA published a draft guidance entitled "Guidance for Industry: Ingredients Declared as Evaporated Cane Juice" in the *Federal Register* (74 FR 51610) to advise industry of FDA's view that the common or usual name for the solid or dried form of sugar cane syrup is "dried cane syrup," and that sweeteners derived from sugar cane syrup should not be declared on food labels as "evaporated cane juice" because that term falsely suggests the sweeteners are juice. On March 5, 2014, we reopened the comment period (79 FR 12507) for the draft guidance seeking further comments, data, and information about how the ingredient sometimes declared as "evaporated cane juice" is produced, what its basic nature and characterizing properties are, and how it compares with other sweeteners made from sugar cane. We received numerous comments on the draft guidance. The majority of comments objected to the term "dried cane syrup." Several comments from sugar producers asserted that this term does not accurately describe the ingredient they produce, mostly because the standardized food "cane syrup" is not the starting material or an intermediate step for the ingredient they refer to as "evaporated cane juice." Based on comments stating that the ingredient sometimes declared as evaporated cane juice is not made from cane syrup as defined in 21 CFR 168.130, FDA is no longer recommending that this ingredient be labeled as "dried cane syrup."

Many comments described the process used to manufacture the ingredient described as "evaporated cane juice," and some comments also described the manufacturing process for other products derived from sugar cane. The initial processing steps are generally the same for all products produced from sugar cane. After sugar cane is harvested, it is cut or shredded and then crushed to extract the fluid. The extracted fluid is clarified and then evaporated to concentrate

[2] Honig, P. Principles of Sugar Technology. Elsevier Publishing Company. 1953.

the solids. To make the product "evaporated cane juice," the concentrated cane extract is filtered and undergoes a single crystallization process. The crystals are then separated from the molasses using centrifugation. From the comments, the method of filtering the "evaporated cane juice" fluid varies from producer to producer, as does the method used for single crystallization.

Most other common types of cane sugar (e.g., white sugar, brown sugar) are not filtered prior to the first crystallization. After the crystals are separated from the molasses using centrifugation, as part of the refining process, the sugar is melted and re-crystallized. Most cane-based sweeteners, including white sugar, undergo multiple crystallization steps.

Some comments stated that "evaporated cane juice" has essentially the same composition as white sugar and other sweeteners derived from sugar cane. As support for this point, one comment provided a specification sheet for "evaporated cane juice" indicating that the ingredient contains between 99.0 and 99.8% sucrose. The comment also included a specification sheet for another product identified as "certified organic sugar" and pointed out that the composition of the two products was identical except that the organic ingredient was made with organic sugar cane. Other comments focused on the differences between "evaporated cane juice" and other cane-based sweeteners. For example, some of these comments stated that "evaporated cane juice" has a different composition from white sugar because it retains traces of molasses and minerals. A few comments said that "evaporated cane juice" is different than other less refined, "alternative" sugars because it contains less molasses and can be substituted for white sugar in processed foods without affecting the taste or appearance of the finished product.

III. Discussion

This guidance is intended to help consumers make informed choices among sweeteners by promoting accurate and consistent labeling. To that end, we are advising the regulated industry of our view that the term "evaporated cane juice" is not the common or usual name of any type of sweetener and that this ingredient should instead be declared on food labels as "sugar," preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses (e.g., "cane sugar").

In developing this guidance, FDA reviewed the Codex Alimentarius Commission's (Codex's) Standard for Sugars, Codex Stan. 212-1999 (Ref. 4), which provides standards for certain sugars intended for human consumption without further processing, to determine whether Codex had established a standard for a product similar to that described on some U.S. food labels as "evaporated cane juice." The Codex Standard for Sugars contains no product identified as "evaporated cane juice." However, the Codex standard does define "raw cane sugar"[3] as "[p]artially purified sucrose, which is crystallised from partially purified cane juice, without further purification, but which does not preclude centrifugation or drying, and which is

[3] The Codex's definition of "raw cane sugar" refers to a different product than "raw sugar" as FDA uses that term. As used in FDA's Compliance Policy Guide (CPG) entitled "Raw Sugar," that term refers to "the intermediate food product as it leaves the sugar factory mill for further refinement in sugar refineries before use as food. In general, raw sugar is unsuitable for human food use because it contains extraneous impurities which are removed in the refining process." CPG 515.400; revised March 1995.
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074439.htm

characterised by sucrose crystals covered with a film of cane molasses." This standard appears to describe the same sweetener referred to in many of the comments as "evaporated cane juice." We agree that the common or usual name used to describe this ingredient on food labels should include the term "sugar" because that term describes the basic nature and characterizing properties of the food.

In contrast, the term "evaporated cane juice" describes neither the basic nature of the food nor its characterizing properties, and therefore does not comply with 21 CFR 102.5(a). "Juice" is defined by 21 CFR 120.1(a) as "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree." This relatively narrow definition is the one used for purposes of the juice hazard analysis and critical control point (HACCP) regulations (21 CFR Part 120) and the juice labeling regulation in 21 CFR 101.30. There are broader definitions of "juice" that are used in other contexts. For example, in the context of botany and food technology, "juice" is a general term referring to the fluid extract of any plant.[4] However, in the context of diet and nutrition, "juice" has the narrower meaning reflected in the definition of "juice" in 21 CFR 120.1(a), which covers only liquid obtained from fruits or vegetables. Although we do not dispute that sugar cane is a member of the vegetable kingdom in the broad sense of classifying an article as "animal," "vegetable," or "mineral," FDA considers the term "vegetable" in the context of the juice definition to refer more narrowly to edible plant parts that consumers are accustomed to eating as vegetables in their diet. Sugar cane is not a vegetable in this sense. While consumers can purchase pieces of sugar cane, consumers do not eat sugar cane as a "vegetable" but instead use it as a source of sugar by chewing on the cane or its fibers or by placing the cane in a beverage to sweeten it. There are other plant juices used for human food that similarly are not "vegetable juice" or "fruit juice" for purposes of the juice definition; e.g., maple syrup and sorghum syrup. In summary, our view is that the fluid extract of sugar cane is not the juice of a plant that consumers are accustomed to eating as a vegetable in their diet and is not, therefore, "juice" as contemplated by the regulation defining that term (Refs. 1, 3).

Sugar cane is clearly not considered a fruit or vegetable by experts in nutrition and health, nor do those experts consider the fluid extract of sugar cane to be a type of fruit or vegetable juice. Rather, they consider it to be a source of sugar. For example, the Department of Agriculture's Center for Food Policy and Promotion lists "cane juice" and "sugar cane juice" among the many names for added sugars on its dietary guidance Web site for consumers (Ref. 5).[5] A newsletter posted on the Department of Health and Human Services Web site warns that "cane juice" is one of the ingredient names used to hide added sugar in beverages and recommends for health reasons that any fruit juice given to children be 100 percent fruit juice without any form of added sugar, including "cane juice."[6] Dietary advice on health organization Web sites is similar. For

[4] For example, Dictionary.com Unabridged defines "juice" in relevant part as "the natural fluid, fluid content, or liquid part that can be extracted from a plant or one of its parts . . . ." http://www.dictionary.com/browse/juice. Retrieved April 25, 2016.

[5] U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. "Added Sugars." http://www.choosemyplate.gov/added-sugars. Retrieved April 20, 2016.

[6] U.S. Department of Health and Human Services, Office of Head Start, National Center on Health. "Health Services Newsletter: The Role of Drinks with Sugar in Children's Oral Health." February 2015. http://eclkc.ohs.acf.hhs.gov/hslc/tta-system/health/docs/health-services-newsletter-201502.pdf. Retrieved April 20, 2016.

example, the Mayo Clinic Web site lists "cane juice" and "cane syrup" as forms of added sugar that consumers should cut back on for better health and nutrition.[7] None of these Web sites defines sugar cane as a vegetable or classifies the fluid extract of the sugar cane plant as "juice" that counts toward the recommended number of daily fruit and vegetable servings.

In FDA's view, the common or usual name for the ingredient currently labeled as "evaporated cane juice" includes the term "sugar" and does not include the term "juice." The basic nature of the ingredient is that it is a sugar and its characterizing property is that of a sweetener. FDA's food labeling regulations provide that sucrose obtained from sugar cane or sugar beets in accordance with 21 CFR 184.1854 shall be referred to as "sugar" in ingredient labeling (21 CFR 101.4(b)(2)). Section 184.1854(a) describes sucrose as the substance "obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated." Based on the numerous comments indicating that the ingredient declared as "evaporated cane juice" is produced in this manner, it follows that the common or usual name for the product should be or include "sugar." As discussed in the Background section, current names that are used for several other sweeteners made from sugar cane (e.g., turbinado sugar, demerara sugar, and muscovado sugar) are names that have been established by common usage. In each instance, the basic nature of the food is described by use of the term "sugar." FDA would not object to the addition of one or more truthful, non-misleading descriptors before the common or usual name "sugar." Such a descriptor, which could be a coined term, could be used to distinguish the ingredient from white sugar and other sugars on the market by describing characteristics such as source, color, flavor, or crystal size.

Sweeteners derived from sugar cane should not be listed in the ingredient declaration by names such as "evaporated cane juice," which suggest that the ingredients are made from or contain fruit or vegetable "juice" as defined in 21 CFR 120.1. We consider such representations to be false and misleading under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(a)(1)) because they do not accurately describe the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups), as required by 21 CFR 102.5.

Because sweeteners derived from sugar cane are not "juice" as defined in 21 CFR 120.1, they should not be included in the percentage juice declaration on the labels of beverages that are represented to contain fruit or vegetable juice (see 21 CFR 101.30). Section 101.30 requires the percentage of fruit or vegetable juice in beverages purporting to contain such ingredients to be declared on the label of the beverage. FDA would consider a juice product sweetened with an ingredient derived from sugar cane and labeled as 100% fruit juice to be misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because the "100% fruit juice" claim is false and misleading in that the product contains a non-juice sweetener in addition to the juice. FDA would also consider such a product adulterated under section 402(b) of the Act (21 U.S.C. 342(b)) because the sweetener has been substituted for part of the juice.

[7] Mayo Clinic Staff. "Added sugars: Don't get sabotaged by sweeteners." http:/www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/added-sugar/art-20045328. Retrieved April 25, 2016.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of May 12, 2016, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after May 12, 2016.

1. Intergovernmental Ad Hoc Codex Task Force on Fruit and Vegetable Juices, Government Comments, p. 16, September 2000.

2. FDA letter from Martin Stutsman to Dr. Eric Wilhelmsen (Wilhelmsen Consulting), May 8, 2000.

3. FDA letter from Martin Stutsman to Martin Hahn, Esq., March 9, 2001.

4. Codex Standard for Sugars. Codex Standard 212-1999. http://www.fao.org/input/download/standards/338/CXS_212e_u.pdf. Adopted 1999. Amendment 2001. Retrieved April 26, 2016.

5. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. "MyPlate." http://www.choosemyplate.gov. Retrieved April 25, 2016.

"Natural" on Food Labeling

The FDA requests comments on use of the term "natural" on food labeling.

Because of the changing landscape of food ingredients and production, and in direct response to consumers who have requested that the FDA explore the use of the term "natural," the agency asked the public to provide information and comments on the use of this term in the labeling of human food products.

The FDA is took this action in part because it received three Citizen Petitions asking that the agency define the term "natural" for use in food labeling and one Citizen Petition asking that the agency prohibit the term "natural" on food labels. We also note that some Federal courts, as a result of litigation between private parties, have requested administrative determinations from the FDA regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as "natural."

Although the FDA has not engaged in rulemaking to establish a formal definition for the term "natural," we do have a longstanding policy concerning the use of "natural" in human food labeling. The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. However, this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term "natural" should describe any nutritional or other health benefit.

Specifically, the FDA asked for information and public comment on questions such as:

- Whether it is appropriate to define the term "natural,"
- If so, how the agency should define "natural," and
- How the agency should determine appropriate use of the term on food labels.

The comment period closed May 10, 2016. View submitted comments in docket folder FDA-2014-N-1207 (http://www.regulations.gov/#!docketDetail;D=FDA-2014-N-1207) on Regulations.gov.

More in Labeling & Nutrition (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm)

Changes to the Nutrition Facts Label (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm)

Food Labeling Guide (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm)

Topic-Specific Labeling Information (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006864.htm)

Exhibit B

Menu and Vending Machines Labeling Requirements (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm217762.htm)

Small Business Nutrition Labeling Exemption (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006867.htm)

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
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January 6, 2014

The Honorable Yvonne Gonzalez Rogers
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Northern District of California
1301 Clay St., Suite 400S
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The Honorable Jeffrey S. White
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2 Federal Square
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Re: Referrals to the United States Food and Drug Administration in *Cox v. Gruma Corp.*, No. 4:12-cv-6502-YGR (N.D. Cal.), *Barnes v. Campbell Soup Co.*, No. 3:12-cv-05185-JSW (N.D. Cal.), and *In Re General Mills, Inc. Kix Cereal Litigation*, No. 2:12-cv-00249-KM-MCA (D.N.J.)

Dear Judges Gonzalez Rogers, White, and McNulty:

This letter responds to your Orders issued on July 11, July 25, and November 1, 2013, respectively, in the above-referenced cases, which referred the question of whether food products containing ingredients produced using bioengineered ingredients may be labeled "Natural" or "All Natural" or "100% Natural" to the Food and Drug Administration ("FDA" or "agency") for an administrative determination under 21 C.F.R. § 10.25(c). In those cases, the plaintiffs allege that the "Natural," "All Natural," and/or "100% Natural" labeling on the Defendants' products are misleading because the products contain corn grown from bioengineered, genetically modified seeds. The *Cox* and *Barnes* cases were stayed for six months with the potential for a further extension; the *Kix Cereal Litigation* was administratively terminated pending FDA's response to the referrals.

FDA has not promulgated a formal definition of the term "natural" with respect to foods. The agency has, however, stated that its policy regarding the use of the term "natural" on food labeling means that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." *See* 58 Fed. Reg. 2302, 2407 (1993).

If FDA were inclined to revoke, amend, or add to this policy, we would likely embark on a public process, such as issuing a regulation or formal guidance, in order to determine whether to make such a change; we would not do so in the context of litigation between private parties. Issuance of a regulation or guidance document allows an agency to obtain data, information, and views from all stakeholders wishing to engage on an issue. Here, given the complexities of the current request, including the competing concerns among and between stakeholders (e.g., various consumer organizations, diverse industry segments), it would be prudent and consistent with FDA's commitment to the principles of openness and transparency to engage the public on this issue.

We note that defining the term "natural" on food labeling necessarily involves interests of Federal agencies other than FDA, including the United States Department of Agriculture ("USDA"), as well as competing views on the part of stakeholders. FDA has discussed the complexities of such a definition with USDA and both agencies have been considering the issue. Any definition of "natural" on food labeling has implications well beyond the narrow scope of genetically engineered food ingredients about which the Court's referral pertains. For example, if the agencies were to define the term, they would likely need to consider among other things: relevant science; consumer preferences, perceptions, and beliefs; the vast array of modern food production technologies in addition to genetic engineering (e.g., use of different types of fertilizer, growth promotion drugs, animal husbandry methods); the myriad food processing methods (e.g., nanotechnology, thermal technologies, pasteurization, irradiation); and any strictures flowing from the First Amendment. Thus, even if we were to embark on a public process to define "natural" in the context of food labeling, there is no assurance that we would revoke, amend, or add to the current policy, or develop any definition at all. [1]

At present, priority food public health and safety matters are largely occupying the limited resources that FDA has to address foods matters. These matters include developing food safety regulations that implement the FDA Food Safety Modernization Act of 2011, many of which have statutory and/or court-ordered deadlines; issuing nutrition labeling regulations, including regulations that implement the Patient Protection and Affordable Care Act of 2010; other actions with direct public health impact (such as addressing the legal status of partially hydrogenated oils); and numerous other matters, such as responding to outbreaks of food-borne illness and overseeing the safety of imported foods. Because, especially in the foods arena, FDA operates in a world of limited resources, we necessarily must prioritize which issues to address.

[1] FDA was notified by letter dated December 5, 2013, that the Grocery Manufacturers Association ("GMA") intends to file a citizen petition early in 2014 asking FDA to "issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled 'natural.'" For all of the reasons set forth previously, we believe that, if the agency were to decide to examine this policy question, the public would be better served if the agency used its administrative processes, rather than providing a response in the context of private litigation on the issue.

Based on the foregoing considerations, we respectfully decline to make a determination at this time regarding whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled "natural."

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

cc: The Honorable Madeline Cox Arleo
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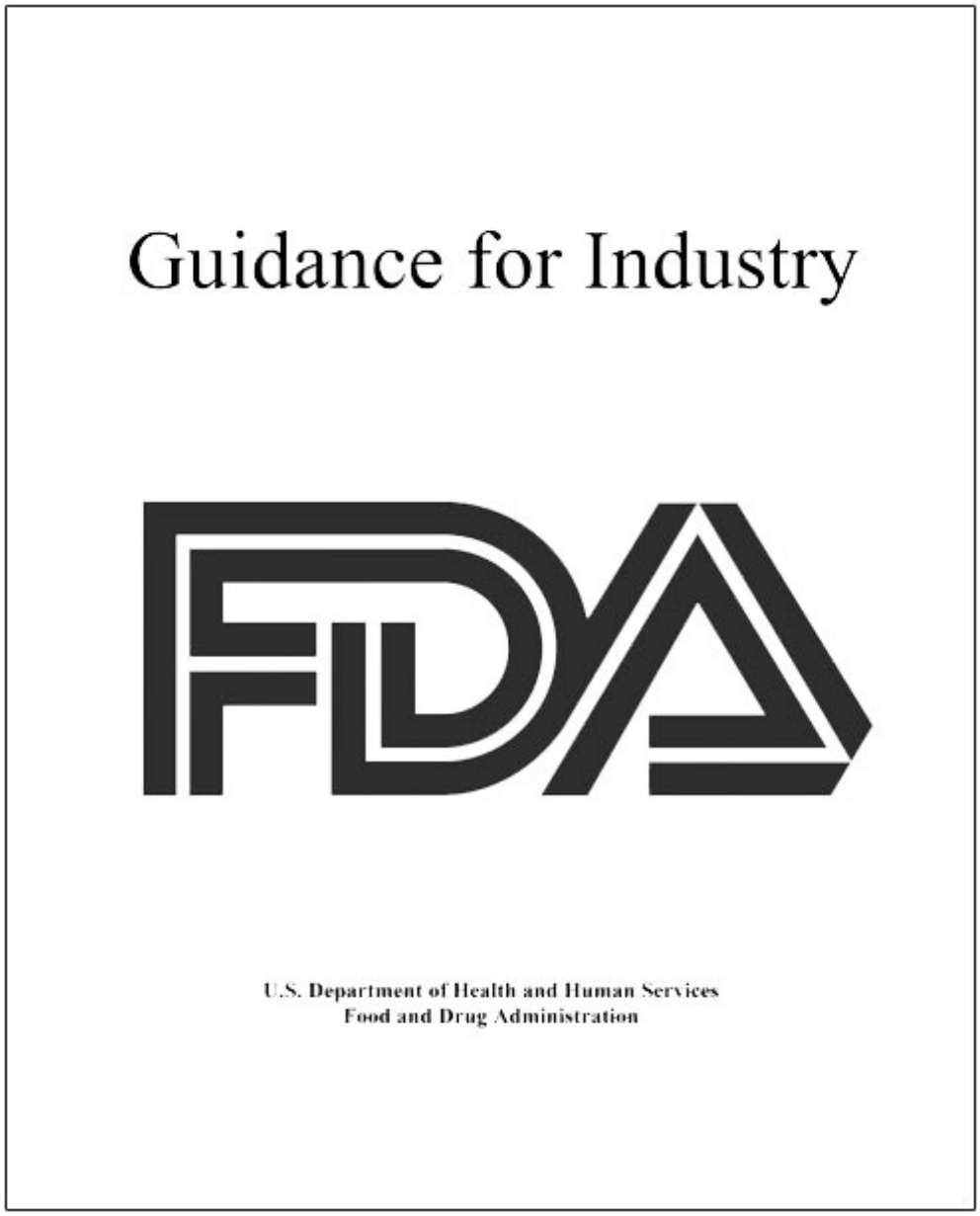
FDA Withdraws 47 "Outdated" Guidance Documents

Posted 05 May 2015

By Alexander Gaffney, RAC (/SearchRegFocus.aspx?name=Alexander Gaffney)

Forty-seven of the US Food and Drug Administration's (FDA) guidance documents were officially declared defunct today after regulators called them unfinished and outdated.

The guidance documents were eliminated in a 5 May 2015 *Federal Register* notice, *Withdrawal of Guidance Published Before December 31, 2013*



(https://www.federalregister.gov/articles/2015/05/06/2015-10477/guidance-withdrawal-of-guidance-published-before-december-31-2013).

The problem, FDA explains in the *Register* notice, is one of transparency and resources. Under FDA's Good Guidance Practices (GGPs), the agency is required to publish most guidance documents in draft form, which allows for the public to offer feedback. After feedback is collected and considered, the guidance document is then published as a "final" guidance document.

However, the feedback process can take months—even years—to complete, and during that time FDA's internal resources and priorities may change. That can leave draft guidance documents languishing in unfinished form for years, even as new scientific developments or broader shifts in policy render them irrelevant.

Those delays aren't uncommon, either. In a March 2015 letter (http://freepdfhosting.com/9d89c19caa.pdf) to Congress, FDA revealed it takes, on average, between 425 days and 797 days to finalize a draft guidance.

How Long Does it Take FDA to Finalize a Draft Guidance Document?

Center	Minimum Days	Maximum Days	Median Days
CBER	261	1.975	743
CDER	194	5,405	710
CDRH	142	2,722	797
CFSAN	90	1,502	454
CVM	238	1,527	477
OSMP	280	2,124	687

When the guidance document development process takes too long, sometimes FDA is left with a document that is neither wanted nor useful to regulators or industry.

Such is the fate of 47 guidance documents FDA says it is immediately "withdrawing."

"Many of these draft guidances were not finalized most often because of higher priorities and resource issues," FDA wrote. "However, over the years, because of new information, scientific developments, and emerging technologies, a number of draft guidances have become outdated and therefore, should be withdrawn."

While the effect of the withdrawals might be relatively small—guidance documents differ from regulations in that they are non-binding and are technically not supposed to be followed until they are made final—the documents cover a large number of products.

There are, for example, guidance documents on advisory committee meetings, bioengineered plants used in medical products, antibiotic resistance markers and gloves used in surgery.

A full list of the withdrawn guidance documents may be found below, or on FDA's website (https://www.federalregister.gov/articles/2015/05/06/2015-10477/guidance-withdrawal-of-guidance-published-before-december-31-2013).

Categories: News (/SearchRegFocus.aspx?catid=471), US (/SearchRegFocus.aspx?catid=509), FDA (/SearchRegFocus.aspx?catid=525)

Tags: Guidance (/SearchRegFocus.aspx?tag=Guidance), Draft Guidance (/SearchRegFocus.aspx?tag=Draft Guidance), Withdrawn Guidance (/SearchRegFocus.aspx?tag=Withdrawn Guidance)

Regulatory Recon: Sanofi and Verily Team up in $500m Diabetes JV; Horizon Buys Raptor for $800m (12 September 2016) (/Regulatory-Focus/News/2016/09/12/25831/Regulatory-Recon-Sanofi-and-Verily-Team-up-in-500m-Diabetes-JV;-Horizon-Buys-Raptor-for-800m-12-September-2016/)

Almost 90% of PMA Applicants Received Major Deficiency Letter on First FDA Review Cycle in 2016 (/regulatoryDetail.aspx?id=25830)

FDA Form 483: Theranos Initiated Trials Without IRB Approval (/Regulatory-Focus/News/2016/09/09/25820/FDA-Form-483-Theranos-Initiated-Trials-Without-IRB-Approval/)

Regulatory Recon: Review Finds Statin Benefits Understated; Pfizer CEO Knocks Clinton's Plan to Curb Drug Price Increases (9 September 2016) (/Regulatory-Focus/News/2016/09/09/25817/Regulatory-Recon-Review-Finds-Statin-Benefits-Understated;-Pfizer-CEO-Knocks-Clintons-Plan-to-Curb-Drug-Price-Increases-9-September-2016/)

Regulatory Exchange: Latest Updates From the Community

Client for Clinical Evaluation Reports (https://connect.raps.org/communities/all-discussions/discussions-moderation/message/?MID=12311)
Any one know a consultant in the Boston area who can quickly turn around a CER according to the new MEDDEV for a single product. I have a small company client needing a referral.

Marion Gordo...

RE: Drug Pedigree Requirements (https://connect.raps.org/communities/all-discussions/discussions-moderation/message/?MID=12310)
Hi David,

Convergence Attendees: Make Your Mark at Member Central (https://connect.raps.org/communities/all-discussions/discussions-moderation/message/?MID=12309)
Hello RAPS Members!

My name is Kelly and I'm the new marketing communications manager for RAPS. I am excited to be heading to San Jose, CA in a few days for my first

RE: Drug Pedigree Requirements (https://connect.raps.org/communities/all-discussions/discussions-moderation/message/?MID=12308)
Hi Catherine,