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MEMORANDUM

From: Elizabeth Barr Fawell
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Re: **COVID-19 Update: FDA Issues Guidance on Temporary Flexibility Policy Regarding Certain Labeling Requirements for Foods for Humans During COVID-19 Pandemic**

On May 22, 2020, the U.S. Food and Drug Administration (FDA) announced two policies to provide temporary flexibility with respect to packaged foods formulation and labeling requirements during the COVID-19 pandemic. 1/ The agency's guidance document is entitled "Temporary Policy Regarding Certain Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines" ("Guidance"). The Guidance details flexibility for manufacturers to make minor formulation changes and flexibility for vending machine operators regarding calorie information for foods sold in vending machines. Like the other guidance documents FDA has issued to provide labeling flexibility during the COVID-19 pandemic, 2/ this guidance is effective only for the duration of the public health emergency. We summarize the Guidance below. 3/

1. Flexibility for Manufacturers to Make Minor Formulation Changes

a. Temporary Policy

The food industry has informed FDA that, as a result of the COVID-19 pandemic, there are supply disruptions or shortages for some ingredients. Therefore, FDA is issuing temporary labeling flexibility in response to requests from the food industry to make minor formulation changes that may cause the finished food label to be incorrect, but that do not pose a health or safety issue and do not

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1/ Guidance for Industry, "Temporary Policy Regarding Certain Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines" (May 2020) https://www.fda.gov/media/138315/download; *see also* FDA Press Release "FDA Announces Temporary Flexibility Policy Regarding Certain Labeling Requirements for Foods for Humans During COVID-19 Pandemic" (May 22, 2020) https://bit.ly/2ZzEPLP.

2/ HL Memo, "FDA Issues Temporary Policy Regarding Labeling of Shell Eggs" (Apr. 3, 2020); HL Memo, "FDA Issues Temporarily Policy for Menu Labeling Requirements and Updates COVID-19 Guidance" (Apr. 2, 2020); HL Memo, "FDA Announces Temporary Flexibility Regarding Nutrition Labeling Due to COVID-19 Pandemic" (Mar. 27, 2020).

3/ This memorandum is offered for general information and educational purposes. It is not offered as, intended as, and does not constitute legal advice. It is not intended to create, and receipt of it does not constitute, a lawyer-client relationship.

cause significant changes in the finished food. Manufacturers should consult the guidance document for full details on the requirements.

In the guidance, FDA announces it does not intend to object to the food industry making certain temporary and minor formulation changes without making conforming label changes when there are supply disruptions or an ingredient shortage exists as a result of the COVID-19 pandemic, subject to certain factors listed below. Nevertheless, the agency "strongly encourage[s] manufacturers to comply with labeling requirements and continue to make conforming label changes when they need to make formulation changes" and notes that labeling alternatives should be used when feasible. Further, FDA recommends alternative methods of communicating changes to consumers, such as manufacturers posting information to their websites or through point of sale labeling.

Minor formulation changes should be made in conformance with the following factors, "as appropriate":

- **Safety:** the ingredient being substituted for the labeled ingredient does not cause any adverse health effect (including food allergens, gluten, sulfites, or other foods known to cause sensitivities in some people, for example, glutamates);

- **Quantity**: generally present at 2 percent or less by weight of the finished food;

- **Prominence:** the ingredient being omitted or substituted for the labeled ingredient is not a major ingredient in the product (such as replacing rice flour for wheat flour in a muffin), or an ingredient that is the subject of a label statement (such as, butter in a cookie with a "made with real butter" claim);

- **Characterizing Ingredient or Ingredient in Name:** the ingredient being omitted or substituted for the labeled ingredient is not a characterizing ingredient (such as omitting raisins in a raisin bread), where the presence of the ingredient has a material bearing on consumer purchasing;

- **Claims:** an omission or substitution of the ingredient does not affect any voluntary nutrient content or health claims on the label; and

- **Nutrition/Function:** an omission or substitution of the labeled ingredient does not have a significant impact on the finished product, including nutritional differences or functionality.

The Guidance also makes note of some existing flexibilities in food labeling regulations, such as the flexibility to declare flavors and spices generically, declare certain colors generically, and in limited cases use "and/or" ingredient labeling.

c. Standardized foods not covered

With the exception of bleached flour, minor formulation changes to food(s) subject to a standard of identity (21 CFR Parts 130 through 169) are not covered by the Guidance.

b. Specific formulation changes

In addition to the general factors noted above, the Guidance comments on a number of specific formulation changes about which the agency does not plan to object. We summarize them here.

- **Reductions and Omissions.** Minor, non-characterizing ingredients may be temporarily omitted from the formulation without corresponding labeling changes being made. Similarly, the amount of a minor ingredient may be temporarily reduced without corresponding labeling

changes being made if the reduction of that minor ingredient does not significantly change the order of predominance in the ingredient list. For example, the reduction or omission of dehydrated vegetables or fruits, such as dehydrated peas in an instant soup, when they are listed on the ingredient list; or the reduction or omission of flavors, spices, colors, oleoresins, or oils, such as vanilla extract in a chocolate chip cookie.

- **Allergens.** FDA recommends that manufacturers avoid making substitutions that could result in a safety concern in countries outside of the United States. Specifically, the Guidance notes that "[i]n addition to the eight major food allergens defined at section 201(qq) of the FD&C Act, several other foods (such as sesame, celery, lupin, buckwheat, molluscan shellfish, and mustard) are recognized as priority allergens in other parts of the world, including Canada, European countries, and Japan."

- **Substitutions of Minor Ingredients at Less Than 2 Percent.** Generally, FDA does not intend to object to "temporary substitutions of non-characterizing ingredients, which are generally present at 2 percent or less, for other safe and suitable ingredients with similar technical functions, as long as there are no safety or allergen concerns introduced." In particular, FDA does not intend to object to the following:

    - **Flavoring.** Substituting a declared artificial flavor for another artificial flavor (such as an "artificial raspberry flavor" for an "artificial berry flavor") or a declared natural flavor for another natural flavor (as long as it is not a characterizing flavor), without a corresponding label change (but FDA notes that substitution of a flavor that poses an allergenic risk without a corresponding label change would not be appropriate).

    - **Spices.** Undeclared substitutions of different spices or changes to the proportion of spices would generally not be a concern if there are no allergens or other spices added that are known to cause sensitivity, such as sesame or mustard.

    - **Colors.** Substituting colors that are not subject to certification for certified colors or if colors that are not subject to certification and are listed by their common or usual name are interchanged without a label change during this time, if the substitution does not pose an allergenic risk.

    - **Acids.** Substituting various acids that are generally recognized as safe, such as lactic, malic, or citric acids, for one another without a label change, as long as they are used in accordance with current good manufacturing practices.

- **Substitutions of Different Varieties of the Same General Ingredient that May be Present at Greater Than 2 Percent.** In the following instances, FDA does not intend to object to the substitution of an ingredient even if it is greater than 2 percent of the product by weight:

    - **Varieties of the Same Ingredient.** FDA does not intend to object to the substitution of an ingredient where the ingredient list includes either a general or specific name of the ingredient (e.g., "Habanero peppers" or "chili peppers"), provided "the substitution does not involve a characterizing ingredient or if there is no reference to the specific variety on the label outside of the ingredient list."

    - **Fats and Oils.** FDA does not intend to object to the use of different fats or oils when the fats or oils are not prominent ingredients, the oils are highly refined, the substitutions do not pose an allergenic risk, the replacement fats or oils are from the same category of vegetable, animal, or marine oils, *and* the oils have a similar fatty

acid profile to minimize the impact on the nutritional profile. For example, substitution of canola oil for sunflower oil may be appropriate without a label change.

- **Geographic Origin.** FDA does not intend to object to temporary substitutions of similar ingredients of different origin if the substitution is not for the food itself. For example, if a food states that it is made with "California raisins" and the manufacturer needs to substitute raisins from another domestic or international location, FDA does not intend to object. Compliance with country of origin labeling under the requirements of the U.S. Department of Agriculture's Agriculture Marketing Service (AMS) and U.S. Customs and Border Protection (CBP) is a separate matter not addressed by this Guidance.

- **Bleached Flour (21 CFR 137).** Given significant supply chain disruptions for the bleaching agent benzoyl peroxide during this time and corresponding bleached flour shortages as a result of the COVID-19 pandemic, FDA does not intend to object to the use of products labeled with "bleached" flour ingredients that substitute for the ingredient "unbleached flour" without making a corresponding label change. This flexibility includes the naming of the finished food bleached flour (and its ingredient statement) as well as the naming of bleached flour as an ingredient in other foods.

2. Flexibility for Vending Machine Operators

FDA does not intend to object if covered vending machine operators do not meet the vending machine labeling requirements under section 403(q)(5)(H)(viii) of the FD&C Act (21 U.S.C. 343(q)(5)(H)(viii)) and 21 CFR 101.8 during the duration of the public health emergency related to COVID-19. FDA recognizes that, as a result of the COVID-19 pandemic, some vending machine operators may need to change business practices in a manner that makes it more difficult to disclose calorie information. For example, some operators may temporarily move vending machines to different locations where essential workers are working, or there may be temporary disruptions in the vended food supply chain which, in turn, affects the availability of standard vending machine items. These situations, and other examples noted in the Guidance, may impact a vending machine operator's ability to declare accurate calorie information for those vending machine foods without making corresponding labeling or signage changes.

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The Guidance is intended to remain in effect only for the duration of the public health emergency. However FDA recognizes that the food and agricultural sector may need additional time to bring its supply chains back into regular order, even after the public health emergency is terminated. Therefore, FDA intends to consider and publicly communicate regarding whether an extension, in whole or in part, is warranted, based on comments received to this guidance and the agency's experience with its implementation.

We will continue to monitor the federal government's response to COVID-19. Should you have any questions or if we can be of assistance with your COVID-19 response strategy, please do not hesitate to contact us.