Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines

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Guidance for Industry

May 2020

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

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or we) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with FDA's good guidance practices.

Comments may be submitted at any time for FDA consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1139 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, the FDA webpage titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to Lynn.Szybist@fda.hhs.gov to receive an additional copy of the guidance. Please include the docket number FDA-2020-D-1139 and complete title of the guidance in the request.

Questions

For questions about this document, contact Lynn Szybist at Lynn.Szybist@fda.hhs.gov.

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Guidance for Industry

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to food manufacturers to provide temporary and limited flexibilities in food labeling requirements under certain circumstances. Our goal is to provide regulatory flexibility, where fitting, to help minimize the impact of supply chain disruptions associated with the current COVID-19 pandemic on product availability. For example, we are providing flexibility for manufacturers to use existing labels, without making otherwise required changes, when making minor formula adjustments due to unforeseen shortages or supply chain disruptions brought about by the COVID-19 pandemic. Additionally, this guidance will provide temporary flexibility to the vending machine industry regarding 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.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS),

including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act (42 U.S.C. 247d(a)(2)).[1] However, we recognize that the food and agricultural sector may need additional time to bring its supply chains back into regular order. Therefore, upon termination of the public health emergency, 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 our experience with its implementation.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with our good guidance practices.

In general, 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 our guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2," and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

In accordance with section 403 of the FD&C Act (21 U.S.C. 343) and with Title 21, Code of Federal Regulations, part 101 (21 CFR part 101) a food is deemed to be misbranded unless its label is truthful and not misleading and bears, among other requirements, a complete list of ingredients and, when applicable, allergen information. Today's food labeling requirements date back to the early 1900s and were intended to prohibit the sale of adulterated products and protect

[1] Generally speaking, section 319(a)(2) of the PHS Act authorizes the Secretary of Health and Human Services to take various actions if the Secretary determines that there is a public health emergency. The provision expressly mentions "significant outbreaks of infectious diseases" as an example of a public health emergency.
[2] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx).
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

consumers from fraudulent or unsafe ingredients. Since 1938, the FD&C Act permitted FDA to create food standards of identity, quality, statement of ingredients, and fill of container for products. Food standards outline recipes for foods and typically set forth ingredients, including fortifying nutrients, that can or must be included in a product. By the 1960s, about half of the food supply was subject to a standard.[4] However, in the late 1960s and early 1970s, the U.S. started to see more processed foods in the marketplace and there was increased consumer demand for information that would help consumers understand the products they purchased.[5] Accurate labels provide important information that empowers consumers when they are making decisions about food. Consumers use the ingredient list to make purchasing decisions and determine whether a food contains an ingredient they want (e.g., whole grains) or ones they do not want (e.g., due to allergies). Without this ingredient information, consumers would not be able make nutrition-based food decisions, as well as avoid ingredients for health or other reasons. Thus, it is fundamental that the labeling flexibilities as set out in this guidance remain in place only as long as needed to help ensure an adequate food supply during and after the pandemic.

As a result of the COVID-19 pandemic, the food industry has informed us that there are supply disruptions or shortages for some ingredients and, as a result, manufacturers will need to make formulation changes, such as omissions or substitutions of minor ingredients, in the manufacturing of some foods. The food industry has advised FDA that they are currently unable to make conforming label changes to reflect these temporary formulation changes without slowing down the flow of production and distribution of some foods. The food industry has requested flexibility when manufacturers need to make such minor formulation changes (discussed further in section III) that may cause the finished food label to be incorrect, but that do not pose a health or safety issue and do not cause significant changes in the finished food due to the temporary formulation modifications.

III. Discussion

Under section 403 of the FD&C Act (21 U.S.C. 343), a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Consumers use information on the food label to make informed choices about the foods they purchase. We strongly encourage manufacturers to comply with labeling requirements and continue to make conforming label changes when they need to make formulation changes due to unforeseen supply disruptions or shortages brought upon by the COVID-19 pandemic. FDA notes that reprinting labels to reflect conforming changes made to product formulations is most desirable to provide consumers with information at the point of sale, and that there are labeling alternatives such as stickers that can be used to inform consumers of any changes.

[4] FDA's Evolving Regulatory Powers Part III: Drugs and Foods Under the 1938 Act and Its Amendments, available at: https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-iii-drugs-and-foods-under-1938-act-and-its-amendments.

[5] WHC (White House Conference on Food, Nutrition, and Health). 1970. *White House conference on food, nutrition, and health: Final report.* 1970. Washington, DC: U.S. Government Printing Office.

However, we recognize that the COVID-19 pandemic is having a substantial impact on food supply chains, and these preferred options may not be feasible given current circumstances. Access to certain ingredients may be challenging during this unprecedented time. The food industry work force may be stretched by illness and the changes to food manufacturing operations that are needed to operate as safely as possible during the pandemic. The application of stickers that inform consumers of the formulation change might not be practicable because of these limited resources. Therefore, to help ensure a national federal policy that supports an adequate food supply during the pandemic, we are providing temporary labeling flexibilities for minor formulation changes under specific circumstances in light of the current situation to help ensure continued production and distribution of food. This means that we do not intend to object if manufacturers make certain temporary and minor formulation changes due to supply chain challenges during this time without making conforming label changes, as explained in this guidance. For transparency and consumer awareness, we recommend that manufacturers use alternative ways, such as posting information to their website or through point of sale labeling, to communicate to consumers any changes, such as ingredient omissions or substitutions, that are not reflected on the product label.

A. Existing Flexibility for Ingredient Statement Labeling Requirements

Manufacturers should be aware that our existing food labeling regulations in 21 CFR 101.4(b) and 101.22 already provide some labeling flexibilities that would not require a label change when a substitution is made. For example, our labeling regulations provide for the use of some generic terms for flavors and spices (21 CFR 101.4(b)(1) and 101.22), while other regulations provide for generic labeling of certain colors (21 CFR 101.22) or the use of "and/or" labeling (see, e.g., 21 CFR 101.4(b)).

B. General Factors for Minor Formulation Changes During the COVID-19 Pandemic

FDA 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. For purposes of this guidance, minor formulation changes should be consistent with the general factors listed below, 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 ingredients known to cause sensitivities (see section C.2.a) in some people, for example, glutamates);
- **QUANTITY**: generally present at 2 percent or less by weight[6] of the finished food;
- **PROMINENCE**: the ingredient being omitted or substituted for the labeled ingredient is not a major (prominent) ingredient (for example, 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);

[6] Title 21 CFR 101.4(a)(2) allows for ingredients present at 2 percent or less by weight to be listed in any order following an appropriate quantifying statement. The terms "minor ingredients" or "low-level ingredients" are used in 55 FR 17431 (April 25, 1990) when describing these ingredients present at 2 percent or less.

- **CHARACTERIZING 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).

See the next section for examples. Minor formulation changes to food(s) that involves a food standard (21 CFR parts 130 through 169) are not covered under this guidance, with the exception of bleached flour (see below).

C. Temporary Flexibility for Labeling Requirements During the COVID-19 Pandemic

1. Reductions and Omissions

Considering the general factors provided in section B, we do not intend to object if minor, non-characterizing ingredients are temporarily omitted from the formulation without corresponding labeling changes being made. Alternatively, we do not intend to object if a manufacturer uses less of a minor ingredient if the reduction of that minor ingredient does not significantly change the order of predominance in the ingredient list. Examples include:

- Reduction or omission of a vegetable (e.g. green peppers) from a vegetable quiche that contains small amounts of multiple vegetables;
- 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
- Reduction or omission of flavors, spices, colors, oleoresins, or oils, such as vanilla extract in a chocolate chip cookie.

2. Substitutions of Minor Ingredients at Less Than 2 Percent

Considering the general factors provided in section III.B., we do not intend to object to substitution of minor ingredients described below in "Examples of Substitutions of Minor Ingredients," where labels would be inconsistent with labeling requirements due to some minor formulation changes that involve 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.

a. Avoidance Considerations

In 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. There are also other ingredients (such as glutamates and sulfites) that can

cause adverse reactions. Manufacturers should avoid substitutions that could result in a safety concern without making a conforming label change or providing other means to inform consumers of the change.

b. Examples of Substitutions of Minor Ingredients

Flavors and Spices

During this time, FDA does not intend to object if a manufacturer chooses to substitute 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. Substitution of a flavor that poses an allergenic risk without a corresponding label change would not be appropriate. For example, some flavors may contain protein from allergens such as milk or peanut.

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

We do not intend to object if colors that are not subject to certification are used in place of 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

FDA does not intend to object if various acids that are generally recognized as safe, such as lactic, malic, or citric acids, are temporarily substituted for one another without a label change, as long as they are used in accordance with current good manufacturing practices.

3. Substitutions of Different Varieties of the Same General Ingredient That May be Present at Greater Than 2 Percent

Varieties of the Same Ingredient

Different varieties of the same ingredient may be substituted without a corresponding label change if the ingredient list uses a general term to declare such an ingredient on the label. For example, a product may declare "mushrooms" in its ingredient list. If one variety of mushroom needs to temporarily be substituted for the typical formulation, such a change would likely still comply with labeling requirements and manufacturers have flexibility to make such changes. However, some manufacturers may choose to specify certain varieties in their ingredient list instead of using a general term (e.g., declaring "Habanero peppers" instead of just "chili peppers" in the ingredient list). In this situation, FDA does not intend to object to certain temporary substitutions of similar ingredients without corresponding labeling changes, even if

the specific variety is declared in the ingredient statement. We acknowledge that, in some cases, the specific variety of an ingredient may be greater than 2 percent by weight for the entire product. However, we are providing flexibility above 2 percent by weight if 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. For example, if the label of a spaghetti sauce makes the statement "made with mushrooms" and the ingredient statement declares portobello mushrooms as an ingredient, we do not intend to object if the firm temporarily needs to use button mushrooms rather than portobello mushrooms. However, if the label of a spaghetti sauce makes the statement "made with portobello mushrooms," a substitution with button mushrooms should not be made unless accompanied by a corresponding label change.

Fats and Oils

FDA does not intend to object to temporary substitutions without a label change of different fats or oils when the fats or oils are not prominent ingredients,[7] 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 (both are vegetable sourced and have similar fatty acid profiles), but the substitution without a label change of beef tallow for sunflower oil would be outside the scope of this policy because the oils are from different categories (one is animal sourced and the other is vegetable sourced) and have different fatty acid profiles.

4. Geographical Origin

Some foods may voluntarily provide the geographical origin of certain ingredients. 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. However, we note that specific inquiries regarding country of origin labeling should be directed to the U.S. Department of Homeland Security's Customs and Border Protection (CBP) and the U.S. Department of Agriculture's Agricultural Marketing Service (USDA/AMS).

5. Bleached Flour (21 CFR 137)

Some flours, including enriched flour, are standardized foods under 21 CFR part 137, Cereal Flours and Related Products. The flour standards allow for the addition of bleaching ingredients in accordance with the applicable regulations. When a flour is bleached, the bleaching ingredient is declared in the ingredient statement and the word "Bleached" must immediately and conspicuously precede or follow the name of the food (21 CFR 137.105(b)(2)). As a result of the

[7] Under 21 CFR 101.4(b)(14), fats and/or oils are considered a predominant ingredient for products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil.

COVID-19 pandemic, we are aware that there are challenges obtaining the bleaching agent benzoyl peroxide. Given significant supply chain disruptions for this ingredient during this time, we do 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 while there continues to be "bleached" flour shortages as a result of the COVID-19 pandemic. 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. We note that the use of bleaching ingredients is for aesthetic purposes in flour and poses no safety issues or nutritional differences in the food.

IV. Vending Machine Labeling

Additionally, we have also heard from the vending machine industry that some temporary flexibility may be necessary for the calorie declarations required 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 due to temporary changes in business practices or disruptions in the vended food supply chain.

FDA is also issuing this guidance to provide flexibility to vending machine operators who own or operate 20 or more vending machines under the vending machine labeling provisions of section 403(q)(5)(H)(viii) of the FD&C Act (21 U.S.C. 343(q)(5)(H)(viii)) during the COVID-19 pandemic. Section 403(q)(5)(H)(viii) of the FD&C Act generally requires operators who own or operate 20 or more vending machines to disclose calorie information for food sold from vending machines, subject to certain exemptions. FDA regulations implementing the vending machine labeling requirements can be found at § 101.8 (21 CFR 101.8).

There is a range of methods of how vending machine operators can display calories for vended foods, such as, electronic vending machines with digital or electronic or LCD (liquid crystal displays), signs or stickers. Some of these vending machines are located in hospitals, emergency dispatch centers, police stations, firehouses, truck stops, and rest areas stocked with food necessary for essential response individuals or teams. However, as a result of the COVID-19 pandemic, some vending machine operators may need to change business practices. For example, some vending machine operators may need to temporarily move vending machines to different locations where essential workers are working and there may be temporary disruptions in the vended food supply chain which, in turn, affects the availability of standard vending machine items. Some vending machine operators may experience staffing issues which affects their ability to update or revise displays. Other vending machine operators may experience difficulties in replacing stock, necessitating product substitutions using products that lack front of package calorie information. These situations 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.

While we encourage covered vending machine operators to continue to comply with the vending machine labeling requirements, to help vending machine operators address temporary business practice changes as a result of the COVID-19 public health emergency, we do 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.