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Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency

Guidance for Industry

March 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. As discussed in the *Federal Register* of March 25, 2020, 85 FR 16949, this is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) 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 the Agency's good guidance practices.

Comments may be submitted at any time for Agency 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>, and the FDA Webpage titled "Guidance Documents and Regulatory Information by Topic (Food and Dietary Supplements)," available at <https://www.fda.gov/FoodGuidances>.

Questions

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) 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 or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including 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 provide restaurants and food manufacturers with flexibility regarding nutrition labeling so that they can sell certain packaged foods during the COVID-19 pandemic. This guidance does not apply to foods prepared by restaurants.

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)(i) 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 the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

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requirements are cited. The use of the word *should* in Agency 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, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

As a result of the COVID-19 pandemic, restaurants may have purchased food, including ingredients, that they can no longer use to prepare restaurant food and instead wish to sell directly to consumers or to other businesses. Generally, restaurants follow food safety requirements in state, local, tribal, and territorial food safety laws that are modeled after FDA’s Food Code. We believe these requirements, which include specifications on temperature at receipt and holding specifications to ensure the food is safe and unadulterated, are adequate to ensure the safety of the food while at a restaurant, such that the food could go back into distribution.

Similar to the situation in restaurants, food manufacturers may have inventory on hand that is labeled for use in restaurants that is no longer being purchased by those operations. In addition, because many manufacturers practice “just in time” manufacturing, they may have sufficient ingredients on hand to produce additional product but not enough packaging materials to label the product for retail sale.

III. Discussion

Labeling by Restaurants

Food purchased by restaurants to be used to prepare restaurant food, and not for distribution to consumers, may not contain the Nutrition Facts label and therefore restaurants may receive such food without nutrition information. However, if restaurants sell packaged food to consumers directly or to other businesses for sale to consumers, nutrition information may be required (see 21 CFR 101.9(a)(1) and 101.9(j)(2)). To facilitate the further distribution of food during the COVID-19 pandemic, FDA does not intend to object to the sale of packaged food (both perishable and non-perishable food) that lacks a Nutrition Facts label by restaurants, provided that the food does not have any nutrition claims and contains other required information on the label, including the following, as applicable:

¹ Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² 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/>.

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- a statement of identity,
- an ingredient statement,
- the name and place of business of the food manufacturer, packer, or distributor,
- net quantity of contents, and
- allergen information required by the Food Allergen Labeling and Consumer Protection Act.

The restaurant may reuse original labels or provide the above information on labels it creates or that are provided by the manufacturer.

Labeling by Food Manufacturing Facilities

To facilitate the distribution of food during the COVID-19 pandemic from food manufacturers that have inventory on hand that is labeled for use in restaurants, FDA does not intend to object to the sale of packaged food that lacks a Nutrition Facts label by food manufacturers, provided that the food does not have any nutrition claims and contains other required information on the label, including the following, as applicable:

- a statement of identity,
- an ingredient statement,
- the name and place of business of the food manufacturer, packer, or distributor,
- net quantity of contents, and
- allergen information required by the Food Allergen Labeling and Consumer Protection Act.

Labeling if Retail Packaging is Unavailable

Finally, to facilitate the distribution of food during the COVID-19 pandemic if retail packaging for certain food products is unavailable, FDA does not intend to object to the further production of food labeled for use in restaurants that is intended to be sold other than to restaurants until retail packaging is available.

The policies in this guidance are intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act.