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Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency

Guidance for Industry

April 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and 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 the Agency 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 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, the Agency, or we) 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 chain restaurants and similar retail food establishments that sell standard menu items¹ covered under the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide flexibility regarding these menu labeling requirements during the COVID-19 pandemic.

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.

¹ A “standard menu item” is defined as a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display (21 CFR 101.11(a)).

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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-2020-0325/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 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, guidance documents describe the Agency’s 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 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.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³

Section 403(q)(5)(H) of the FD&C Act (21 U.S.C. 343(q)(5)(H)) requires restaurants and similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items to provide nutrition information (including calorie declarations) for standard menu items on menus and menu boards so that the information be available to customers when they make their order selections. However, as a result of the COVID-19 pandemic, some chain restaurants and similar retail food establishments are temporarily changing business practices to address the pandemic’s impact on operations. For example, some dine-in operations are temporarily switching to a takeout or “to-go” only format in response to the COVID-19 restrictions which involves creating new or modified online ordering portals and printed takeout or to-go menus for their stores. Additionally, some chain restaurants and similar retail food establishments may be experiencing temporary disruptions in the food supply chain which may impact availability of their standard menu items.

III. Discussion

In 2010, the FD&C Act was amended to require, in part, that chain restaurants or similar retail food establishments:

² 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>.

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/>.

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- Post calorie information on menus and menu boards for all standard menu items;
- Disclose calorie information on signs adjacent to foods on display and self-service foods that are standard menu items;
- Include a succinct statement⁴ concerning suggested daily caloric intake and a statement of availability for written nutrition information on menus and menu boards⁵; and
- Have required written nutrition information available on the premises of the chain restaurant or similar retail food establishment upon request.

To implement the menu labeling provisions of the FD&C Act, on December 1, 2014, FDA issued a final rule on nutrition labeling of standard menu items in chain restaurants and similar retail food establishments; the rule is codified at 21 CFR 101.11.

While we encourage covered establishments to continue to comply with the menu labeling requirements, to help chain restaurants and similar retail food establishments address temporary business practice changes as a result of the COVID-19 public health emergency, we do not intend to object if covered establishments do not meet the menu labeling requirements under section 403(q)(5)(H) of the FD&C Act (21 U.S.C. 343(q)(5)(H)) and our regulation at 21 CFR 101.11 during the duration of the public health emergency related to COVID-19. Covered establishments will be required to comply with the menu labeling requirement set out at 21 CFR 101.11 upon conclusion of the public health emergency.

⁴ The implementing regulations state that the statement must read: “2,000 calories a day is used for general nutrition advice, but calorie needs vary.” (21 CFR 101.11(b)(2)(i)(B)).

⁵ The implementing regulations state that menus and menu boards must provide the following statement regarding the availability of additional written nutrition information: “Additional nutrition information available upon request” (statement of availability). (21 CFR 101.11(b)(2)(i)(C)).