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Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by 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 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)(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 FDA's good guidance practices.

Comments may be submitted at any time for our 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/coronavirus-disease-2019-covid-19>, 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 "Food Labeling & Nutrition," available at <https://www.fda.gov/food/food-labeling-nutrition>.

Questions

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Guidance for Industry

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 or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or we) 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 continuity and response efforts to this pandemic.

FDA is issuing this guidance to provide temporary flexibility regarding certain packaging and labeling requirements for shell eggs sold in retail food establishments so that industry can meet the increased demand for shell eggs 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.

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

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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, guidances 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 our guidance documents means that something is suggested or recommended, but not required.

II. Background

There is currently a pandemic respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (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

Generally, retail food establishments receive shell eggs from their suppliers in cartons which are labeled for retail sale in accordance with FDA's food labeling requirements in Title 21, Code of Federal Regulations, part 101 and section 403 of the FD&C Act (21 U.S.C. 343). Egg cartons must include a statement of identity (21 CFR 101.3); the name and place of business of the manufacturer (the shell egg producer), packer or distributor (21 CFR 101.5); nutrition labeling (21 CFR 101.9); the net quantity of contents (21 CFR 101.7); and safe handling instructions (21 CFR 101.17(h)).³

As a result of the COVID-19 pandemic, consumer demand for shell eggs has increased. Additional shell eggs for consumers are available, but appropriately labeled retail packaging is not available for all such shell eggs. To meet the increased demand for shell eggs in light of the limited availability of retail packaging, we are providing temporary flexibility regarding certain packaging and labeling requirements for shell eggs so that industry can meet the increased consumer demand.

On March 26, 2020, FDA released a guidance document titled, [Guidance for Industry: Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency](#), to facilitate distribution of food during the COVID-19 pandemic by providing flexibility regarding nutrition labeling of certain packaged food. In that guidance, we stated that we do not intend to object if packaged food lacks a Nutrition Facts label, provided certain circumstances are present. That guidance does not address the retail sale of unpackaged shell eggs or the use of shell egg cartons that do not have labels.

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/>.

³ Ingredient labeling and allergen information are not concerns for shell eggs because they are single-ingredient foods and raw agricultural commodities (see section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)).

III. Discussion

To facilitate the distribution of shell eggs during the COVID-19 pandemic, FDA does not intend to object to the sale by retail food establishments of shell eggs in cartons or flats without labels, provided the following circumstances are present:

- The retail food establishment displays clearly at the point of purchase (for example, on a counter card, sign, tag affixed to the product, or some other appropriate device) the following information:
 - Statement of identity,
 - The name and place of business of the manufacturer, packer, or distributor, and
 - Safe handling instructions for shell eggs that have not been processed to destroy all viable *Salmonella*.
- If shell eggs from multiple suppliers are offered for sale at the same time and in the same location, it is clear to consumers which point of sale labeling applies to which of the shell eggs that are offered for sale.
- The shell eggs are sold by the complete carton or flat (for example, 30 eggs are sold in a flat designed to hold 30 eggs).
- There are no nutrition claims at the point of purchase for the shell eggs.

As availability of packing and labeling materials improves, we encourage industry to resume full labeling as soon as practicable.