DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2010-D-0575 and FDA-2021-N-0764]

Compliance Policy Guide Sec. 510.800 Beverages--Serving Size Labeling; Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp--Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations; and Compliance Policy Guide Sec. 562.800 Vending Machine Food--Labeling; Withdrawal of Guidances AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of three compliance policy guides (CPG) entitled "Compliance Policy Guide Sec. 510.800 Beverages--Serving Size Labeling," "Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp--Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations," and "Compliance Policy Guide Sec. 562.800 Vending Machine Food--Labeling." We are withdrawing these CPGs because they have become outdated or have been superseded by subsequent FDA actions.

DATES: The withdrawal is applicable [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert docket number FDA-2010-D-0575 for "Compliance Policy Guide Sec. 510.800 Beverages--Serving Size Labeling" or FDA-2021-N-0764 for "Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp--Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations" and "Compliance Policy Guide Sec. 562.800 Vending Machine Food--Labeling" into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Kevin Kwon, Office of Compliance (HFS-605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-4597; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the withdrawal of three CPGs entitled "Compliance Policy Guide Sec. 510.800 Beverages--Serving Size Labeling," "Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp--Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations," and "Compliance Policy Guide Sec. 562.800 Vending Machine Food--Labeling."

CPG Sec. 510.800 entitled "Beverages--Serving Size Labeling" was first issued in December 2010. This CPG provided guidance for FDA staff and industry as to when we would typically consider not taking enforcement action in connection to a "12 [fluid ounce] (360 [milliliter])" labeled serving size on specific types of beverages larger than 20 fluid ounces. On May 27, 2016, FDA issued a final rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (81 FR 34000). The final rule amended the Reference Amounts Customarily Consumed (RACCs) that are used by manufacturers to determine serving sizes for certain foods, including certain beverages. Our regulations, at 21 CFR 101.12(b), table 2, lists the categories for each type of food product and each category's current RACC. Due to the updated RACCs for certain beverages, CPG Sec. 510.800 is now obsolete, and the enforcement discretion provided in this CPG is no longer applicable. Therefore, CPG Sec. 510.800 is being withdrawn.

CPG Sec. 540.420 entitled "Raw Breaded Shrimp--Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations" was first issued in August 1983. This CPG used data collected in fiscal year 1978 and listed an outdated sampling and compliance structure. The compliance criteria and the methodology used in the CPG have become outdated and are no longer useful. This CPG is superseded by the Seafood Hazard Analysis Critical Control Point regulation in 21 CFR part 123. Seafood processors must prevent food safety hazards using critical controls and appropriate verification activities, such as end-product and in-process testing (21 CFR part 123). This CPG is also superseded by FDA's Fish and Fishery Products Hazards and Controls Guidance (Ref. 1), which describes controls for food safety hazards related to breaded shrimp. For these reasons, CPG Sec. 540.420 is now obsolete and is being withdrawn.

CPG 562.800 entitled "Vending Machine Food--Labeling" was first issued in September 1976. This CPG provided guidance for FDA staff and industry regarding certain mandatory label information for foods and beverages dispensed in vending machines after movement in interstate commerce.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act of 2010 (ACA; Pub, L, 111-148) into law. Section 4205 of the ACA amended section 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)) and section 403A of the FD&C Act (21 U.S.C. 343-1), which governs Federal preemption of State and local food labeling requirements. Section 4205 of the ACA added section 403(q)(5)(H)(viii) to the FD&C Act to require that if an article of food is sold from a vending machine that (1) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and (2) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, then the vending machine operator must provide a sign in close proximity to each

article of food or the selection button that includes a clear and conspicuous statement disclosing

the number of calories contained in the article of food.

In the Federal Register of December 1, 2014 (79 FR 71259), we issued a final rule to

implement these labeling requirements; the regulations are codified at 21 CFR 101.8. With this

regulatory change, CPG 562.800 is now obsolete and is being withdrawn.

II. Reference

The following reference is on display at the Dockets Management Staff (see

ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m.,

Monday through Friday; it is also available electronically at https://www.regulations.gov.

1. FDA, "Fish and Fishery Products Hazards and Controls Guidance, 4th Edition," June

2021.

Dated: February 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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