UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, 1220 L Street, N.W., Suite 300 Washington, D.C. 20005; and NATIONAL CONSUMERS LEAGUE, 1701 K Street, N.W., Suite 1200 Washington, D.C. 20006; Plaintiffs, v. DR. TOM PRICE, Secretary of the Department of Health and Human Services; DR. SCOTT GOTTLIEB, Commissioner of the United States Food and Drug Administration; and the UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendants.	Civil Action No. _____

COMPLAINT

INTRODUCTION

1. Plaintiffs Center for Science in the Public Interest ("CSPI") and National Consumers League ("NCL") (collectively, "Plaintiffs") challenge a rule issued by Defendants Dr. Tom Price, Dr. Scott Gottlieb, and the U.S. Food and Drug Administration (collectively, "FDA"), which delays the compliance deadline of a prior rule requiring chain restaurants and similar retail food establishments to disclose calorie contents and other health information for standard menu items ("Nutrition Labeling Rule"). *See* Food Labeling; Nutrition Labeling of

Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825 (May 4, 2017) ("Delay Rule"). A copy of the Delay Rule is attached hereto as Exhibit A.

2. The Nutrition Labeling Rule requires certain chain restaurants, supermarkets, convenience stores, movie theaters, and similar food retail establishments to display the calorie content of standard menu items and provide information about calories from fat, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in writing upon request. As the FDA recognized in issuing the Nutrition Labeling Rule over two and a half years ago, these requirements "give consumers much needed access to essential nutrition information for a large and growing number of the foods they purchase and consume." Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; 79 Fed. Reg. 71,156, 71,161 (Dec. 1, 2014).

3. Nutrition labeling at restaurants and similar food retail establishments has been demonstrated to make an important difference in the ability of consumers to take control of their health, and thus on the health of Americans.

4. On average, Americans consume one-third of their total calories away from home. Typical consumers—and even well trained nutrition professionals—often vastly underestimate the calorie content and associated health consequences of foods served in restaurants and similar establishments. As a result in part of these trends, two-thirds of U.S. adults and one-third of U.S. children are overweight or obese. Many others struggle to control their weight, reduce their risk of chronic disease, and manage existing health conditions. Diseases associated with poor diet and obesity kill more than half a million Americans each year. Due to high rates of obesity, today's children risk living shorter, less healthy lives than their parents.

5. Nutrition labeling assists in managing and reducing other health risks in addition to obesity. According to the 2015-2020 Dietary Guidelines for Americans, the federal government advises Americans to limit their consumption of "[s]aturated fats and *trans* fats, added sugars, and sodium," all of which pose "particular public health concern in the United States." U.S. Dep't of Health and Human Servs. and U.S. Dep't of Agriculture, *2015-2020 Dietary Guidelines for Americans* 15 (Dec. 2015), https://health.gov/dietaryguidelines/2015/guidelines/.

6. Based on consumer interest in increased availability of calorie and other nutrition information, the demonstrated health risks posed by excessive consumption of calories and certain nutrients, and the demonstrated effectiveness of nutrition labeling, the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 4205, 124 Stat. 119, 573-576 (2010) (codified in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(q)(5)(H)), required the FDA to promulgate a nutrition labeling rule. The FDA did so in December 2014.

7. Pursuant to the Nutrition Labeling Rule, chain restaurants and similar establishments were to begin providing specified nutrition information on menus and elsewhere by December 2015.

8. However, the compliance date for the Nutrition Labeling Rule has been repeatedly delayed, so that consumers are still deprived of the important health information that Congress determined they deserve over seven years ago.

9. This lawsuit challenges the most recent delay of the compliance date in the Delay Rule. On May 4, 2017—one day before chain restaurants and similar establishments were to begin providing calorie and other nutrition information to consumers—the FDA published the

Delay Rule, which immediately postponed the Nutrition Labeling Rule's compliance deadline for another year to May 7, 2018.

10. The FDA's promulgation of the Delay Rule constitutes an unlawful amendment of the Nutrition Labeling Rule, a final rule duly promulgated under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq*. ("APA"). The FDA violated the APA by departing from its prior interpretation of the ACA and its prior conclusions about the importance of nutrition labeling without providing a rational explanation.

11. In addition, the FDA violated the APA by issuing the Delay Rule—a final agency action with legally binding effect—without complying with mandatory rule making procedures, including advance notice and an opportunity for public comment before the Delay Rule took effect.

12. Plaintiffs respectfully request that the Court hold the Delay Rule to be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and to have been published without observance of legally required procedure, in violation of the APA. In addition, Plaintiffs seek an order vacating the Delay Rule and declaring that compliance with the Nutrition Labeling Rule is required by a date certain, not to exceed 15 days after the Court's Order is issued.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question) and 1361 (action to compel performance of a mandatory duty).

14. The Delay Rule is a final agency action subject to judicial review. 5 U.S.C. §§ 702, 704, 706.

15. Plaintiffs have a right to bring this action under the APA. *Id.* §§ 701–706.

16. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201. This Court has authority to issue the relief requested under 28 U.S.C. §§ 2201–02 (declaratory judgment and further relief).

17. Venue is proper in the District of Columbia pursuant to 28 U.S.C. § 1391(e)(1), because Defendants reside in this district and the Delay Rule was issued in this district.

PARTIES

18. Plaintiff Center for Science in the Public Interest is a non-profit organization dedicated to obtaining a healthier food system. Since 1971, CSPI has worked to educate its members and the public at large about health, nutrition, and food safety; advocate for government policies that are consistent with scientific evidence; and counter industry's powerful influence on public opinion and public policies. Among CSPI's many accomplishments are its successful efforts to remove soda from schools and remove harmful *trans* fats from the food supply. CSPI maintains NutritionAction.com and publishes *Nutrition Action Healthletter*, which provides science-based advice on health and nutrition to its approximately 600,000 members and supporters. These members and supporters, who collectively contribute about 75 percent of the CSPI's budget, are deeply concerned about health, nutrition, and food safety. CSPI and its members and supporters actively engaged in the multi-year administrative process that culminated in the development of the Nutrition Labeling Rule.

19. Founded in 1899, Plaintiff National Consumers League is America's pioneering non-profit consumer advocacy organization. For nearly 120 years, NCL has worked to promote fairness and economic justice for consumers and workers in the United States and abroad. To this end, NCL appears regularly before legislatures, administrative agencies, and courts across the country, advocating for the enactment and vigorous enforcement of laws that effectively

provide truthful and accurate information to consumers about the products and services they purchase and use. NCL's Food Policy Program focuses specifically on obtaining a safe, nutritious, and abundant food supply, with access to healthy food at reasonable prices. To ensure that Americans possess the information necessary to make smart decisions about nourishing their families, NCL supports and devotes resources to ensure the full and accurate labeling of foods, including the disclosure of calorie contents and other nutrition information.

20. Plaintiffs bring this action on their own behalf and on behalf of their members and supporters. Plaintiffs have been and will continue to be injured by the FDA's decision to issue the Delay Rule. Plaintiffs have long advocated for greater transparency about the nutritional content of menu items offered at chain restaurants and similar retail food establishments. Without access to this information, Plaintiffs are hindered in their ability to educate the public about healthful and nutritious food and beverage choices, advocate for government policies that support access to healthful and nutritious food, and urge restaurants and similar establishments to introduce and promote healthful and nutritious options. As a result of the Delay Rule, Plaintiffs have diverted—and will continue to divert—staff time and other resources to efforts that would have been unnecessary had restaurants and other establishments started providing calorie and nutrition information as scheduled, thus diminishing Plaintiffs' ability to carry out other activities and programs central to their missions. These injuries are actual, concrete, and irreparable. Plaintiffs will continue to be harmed by the FDA's unlawful actions unless and until this Court provides the relief prayed for in this complaint.

21. The Delay Rule also injures Plaintiffs by depriving their members and supporters of information that federal law gives them the right to know. Together, Plaintiffs have hundreds of thousands of members and supporters, many of whom rely on nutrition labeling—where it is

available pursuant to local laws—to control their weight and to manage or reduce their risk of disease. Many other members and supporters would use this information if it were available at the chain restaurants and similar retail food establishments where they purchase food. Plaintiffs' members and supporters who frequent establishments not subject to local nutrition labeling rules lack sufficient information to make safe, healthful, and nutritious choices for themselves and their families. The FDA's decision to issue the Delay Rule harms Plaintiffs' members and supporters by failing to ensure nationwide access to calorie contents and other nutrition information for an additional year or possibly longer—more than seven years after Congress passed a law requiring chain restaurants and similar retail food establishments to disclose this information. This harm would be redressed by an Order vacating the Delay Rule and declaring that compliance with the Nutrition Labeling Rule is required by a date certain.

22. In addition, the FDA's failure to comply with mandatory rule making procedures harmed Plaintiffs and their members and supporters by depriving them of their right to comment on the Delay Rule *before* it took effect. If Plaintiffs had the opportunity to comment in advance, they would have opposed the Delay Rule.

23. Finally, the FDA's delay of the nutrition labeling requirement contributes to environmental harms that injure Plaintiffs' members and supporters.

24. Defendant Dr. Tom Price is the Secretary of the United States Department of Health and Human Services ("HHS"). As Secretary, Dr. Price has legal authority for administering and overseeing HHS and its operating divisions, including the United States Food and Drug Administration. Dr. Price is sued in his official capacity.

25. Defendant Dr. Scott Gottlieb is the Commissioner of the United States Food and Drug Administration. As Commissioner, Dr. Gottlieb has legal authority for assuring that the

FDA's activities and policies are in conformance with federal laws and regulations. Dr. Gottlieb is sued in his official capacity.

26. Defendant United States Food and Drug Administration is a federal agency within HHS. The agency is charged with protecting public health, in part, by assuring that the U.S. food supply is safe, sanitary, wholesome, and honestly labeled.

STATUTORY BACKGROUND

I. Patient Protection and Affordable Care Act

27. On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act ("ACA"). Among other requirements, the ACA amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to require that every "restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items" must disclose on its menu and/or menu board the number of calories contained in each standard menu item, along with a "succinct statement concerning suggested daily caloric intake." Pub. L. No. 111–148, § 4205; *see* 21 U.S.C. § 343(q)(5)(H) ("Nutrition Labeling Requirement").

28. The Nutrition Labeling Requirement of the ACA also required restaurants and similar retail food establishments to disclose "in written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, [certain] nutrition information." Pub. L. No. 111–148, § 4205; *see* 21 U.S.C. § 343(q)(5)(H)(ii)(III). Specifically, restaurants must disclose "the total number of calories … derived from any source[] and … derived from the total fat," as well as "the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and

total protein." 21 U.S.C. §§ 21 343(q)(1)(C)–(D), 343(q)(5)(H)(ii)(III).

29. Section 4205(b) of the ACA, now codified at 21 U.S.C. § 343(q)(5)(H)(x)(I), directed the FDA to promulgate regulations implementing the Nutrition Labeling Requirement. *Id.*

30. Section 4205(b) of the ACA, now codified at 21 U.S.C. § 343(q)(5)(H)(x)(II), also directed the FDA to "consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines," in promulgating nutrition labeling regulations.

II. Administrative Procedure Act

31. The APA requires agencies to publish a notice of proposed rule making in the Federal Register and provide an opportunity for public comment before formulating, amending, or repealing a rule, unless the rule constitutes an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice" or "the agency for good cause finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §§ 551(5), 553(b).

32. The APA also requires agencies to publish substantive rules at least 30 days before those rules are to take effect, unless the agency identifies good cause not to do so and publishes that good cause along with the rule. 5 U.S.C. § 553(d)(3).

33. Under the APA, "[t]he reviewing court shall ... hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2).

STATEMENT OF FACTS

I. Public Health and Nutrition Labeling

34. Every year, nearly 700,000 Americans die from diseases associated with unhealthful diets.[1]

35. Two-thirds of U.S. adults and one-third of U.S. children are overweight or obese.[2] Obese individuals have a heightened risk of developing a range of serious health conditions that can result in disability or death, including Type 2 diabetes, heart disease, and certain cancers.[3] According to a study published in the American Journal of Public Health, obesity and overweight accounted for approximately 18 percent of all adult deaths between 1986 and 2006.[4] This percentage will likely increase in the near future, because younger Americans are more likely to be obese, and more likely to have become obese earlier in life, than previous generations.[5] As a result, today's children could live shorter, less healthy lives than their parents.[6]

36. Unhealthful menu offerings and the failure to disclose calorie contents and other nutrition information at restaurants and similar retail food establishments contribute significantly to the current obesity epidemic and interfere with individuals' ability to manage chronic disease.

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[1] Christopher J. L. Murray et al., U.S. Burden of Disease Collaborators, *The State of US Health, 1990-2010: Burden of Diseases, Injuries, and Risk Factors*, 310 J. Am. Med. Ass'n 591, 600 [Fig. 3] (2013), doi:10.1001/jama.2013.13805.

[2] Cynthia L. Ogden et al., *Prevalence of Childhood and Adult Obesity in the United States, 2011-2012*, 311 J. Am. Med. Ass'n 806, 810-11 (2014), doi: 10.1001/jama.2014.732.

[3] *See* S. Jay Olshansky et al., *A Potential Decline in Life Expectancy in the United States in the 21st Century*, 352 New Eng. J. Med. 1138 (2005); U.S. Dep't of Agric. ("USDA") & U.S. Dep't of Health & Human Servs., *Dietary Guidelines for Americans* (2010), https://health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf.

[4] Ryan K. Masters et al., *The Impact of Obesity on US Mortality Levels: The Importance of Age and Cohort Factors in Population Estimates*, 103 Am. J. Pub. Health 1895, 1900 (2013), doi:10.2105/AJPH.2013.301379.

[5] *Id.*

[6] S. Jay Olshansky et al., *supra* note 3, at 1141.

On average, Americans eat one-third of their calories away from home, and studies show that people tend to consume more calories and saturated fat—but fewer fruits, dairy, and whole grains—when eating out.[7] According to a 2011 study, frequent consumption of restaurant meals is associated with risk factors for chronic health conditions, including heart disease and high insulin levels.[8] In particular, children typically consume about 55 percent more calories when they eat a meal at a restaurant compared to a meal at home.[9]

37. Experts recommend that people with certain health conditions monitor their consumption of particular nutrients. For instance, people with high blood pressure are advised to limit their sodium intake, while those with high cholesterol or heart disease are instructed to consume less saturated fat.[10] In addition, many people with diabetes who use insulin need to know the carbohydrate content of the foods they consume in order to administer proper insulin dosages.[11] Without access to nutrition information, individuals with these and other conditions may struggle to make decisions necessary to manage their health while eating out.

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[7] Jessica E. Todd et al., USDA, *The Impact of Food Away from Home on Adult Diet Quality* (Feb. 2010), https://www.ers.usda.gov/webdocs/publications/46352/8170_err90_1_.pdf; Biing-Hwan Lin & Rosanna Mentzer Morrison, USDA, *Food and Nutrient Intake Data: Taking a Look at the Nutritional Quality of Foods Eaten at Home and Away From Home*, Amber Waves (June 5, 2012), https://www.ers.usda.gov/amber-waves/2012/june/data-feature-food-and-nutrient-intake-data/.

[8] Christine Zoumas-Morse et al., *Children's Patterns of Macronutrient Intake and Associations with Restaurant and Home Eating*, 101 J. Am. Dietetic Ass'n 923 (2001), doi: 10.1016/S0002-8223(01)00228-0.

[9] Paul Pisarik, *Compensation for Energy Intake from Fast Food Among Overweight and Lean Adolescents*, 292 J. Am. Med. Ass'n 1304 (2004)., doi: 10.1001/jama.291.23.2828.

[10] Robert H. Eckel et al., *AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines*, 63 J. Am. College Cardiology at Supp. Pt. B (2013), doi: 10.1016/j.jacc.2013.11.003.

[11] Am. Diabetes Ass'n, *Carbohydrate Counting* (last updated Nov. 21, 2016), http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/understanding-carbohydrates/carbohydrate-counting/carbohydrate-counting.html.

38. As the FDA has acknowledged, many consumers underestimate the calorie contents of foods served at restaurants and similar establishments. 79 Fed. Reg. at 71,161. For example, without nutrition labeling, consumers would likely not know (unless they visit company websites) that:

a. A pecan roll from Panera Bread (720 calories) has over 300 more calories than a chocolate pastry (410 calories);

b. The Spinach and Artichoke Dip appetizer from Applebee's (960 calories) has more than twice as many calories as the Chicken Wonton Tacos appetizer (460 calories);

c. A chocolate chip muffin from Whole Foods Market (920 calories) has nearly twice as many calories as a blueberry scone (510 calories) and supplies almost half of a person's suggested daily caloric intake (2,000 calories);

d. A coffee roll from Dunkin' Donuts (390 calories) has 50% more calories than a glazed donut (260 calories);

e. One slice of Costco's cheese pizza (760 calories) is, in fact, more caloric than a slice of its pizza with pepperoni (710 calories), and both options supply more than one-third of a person's suggested daily caloric intake;

f. Even without the buttery topping, a large order of popcorn from Regal Cinemas contains 980 calories or nearly 50 percent of a person's suggested daily caloric intake;

g. A Big Bite Hot Dog & Big Gulp Coke from 7-Eleven (560 calories and 320 calories, respectively), currently advertised for $2.22, provide more than 40 percent of a person's suggested daily caloric intake;

h. A Spicy Chicken Sandwich from Wendy's (510 calories) paired with a medium order of French fries (420 calories) and a large Coke (400 calories) totals more than 60 percent of a person's suggested daily caloric intake;

i. A regular oriental chicken salad from Applebee's (1,420 calories) contains approximately 70 percent of a person's suggested daily caloric intake;

j. A slice of carrot cake from the Cheesecake Factory (1,730 calories) contains more than 80 percent of a person's suggested daily caloric intake;

39. Similarly, without access to written nutrition information, few consumers would guess, for example, that Chili's Mix & Match Fajita Trio with Prime Rib, Seared Shrimp, Pork Carnitas, and flour tortillas has 6,320 milligrams of sodium—more than two-and-a-half times the daily maximum recommended for healthy adults—or that TGI Fridays' Jack Daniels Ribs with Seasoned Fries and Coleslaw has 2,860 milligrams of sodium—more than one-and-a-half times the daily maximum recommended for healthy adults.

40. Even highly educated experts struggle to estimate the calorie content of restaurant meals accurately. For instance, according to a study conducted by Plaintiff CSPI, a group of professional dietitians estimated, on average, that a typical hamburger with a serving of eleven onion rings had 865 calories; in fact, this meal contained a total of 1,550 calories, almost twice the estimated amount.[12]

41. Congress's decision to require nutrition labeling reflects scientific evidence showing that nutrition labeling leads customers to make lower calorie choices for themselves and their children. High-quality studies can measure population-wide changes in consumer buying patterns. For example, a large study that examined transactions at Starbucks stores in New York

[12] Jeffrey Backstrand et al., CSPI, *Fat Chance: A Survey of Dietitians Knowledge of the Calories and Fat in Restaurant Meals* (1997).

City from before its menu labeling policy was enacted to after (January 2008 to February 2009) found a 6 percent decrease in average calories per transaction.[13] In addition, a 2013 study found that consumers purchased 150 fewer calories, on average, when calorie and nutrition information was displayed.[14]

42. Research also demonstrates that nutrition labeling induces restaurants to offer more healthful and nutritious options. For instance, after a local law requiring nutrition labeling took effect, chain restaurants in King County, Washington decreased the calorie content of their entrée items by an average of 41 calories each.[15] A 2015 study that examined 66 of the largest U.S. restaurant chains found that average per-item calorie content was approximately 140 calories lower for restaurants that voluntarily posted information about calories than those that did not between 2012-2014.[16] Between the years of 2005 and 2011, healthier menu items increased from 13 to 20 percent at five fast-food chains subject to nutrition labeling requirements.[17]

43. If replicated nationwide, these reductions would significantly improve public health and reduce health care spending. In its Final Regulatory Impact Analysis for the Nutrition Labeling Rule, the FDA estimated that the benefits of the Nutrition Labeling Rule "for the total

[13] Bryan Bollinger et al., *Calorie Posting in Chain Restaurants,* 3 Am. Econ. J.: Econ. Policy 91 (2011).
[14] Amy H. Auchincloss et al., *Customer Responses to Mandatory Menu Labeling at Full-Service Restaurants,* 45 Am. J. Preventive Med. 710 (2013).
[15] Barbara Bruemmer et al., *Energy, Saturated Fat, and Sodium Were Lower in Entrees at Chain Restaurants at 18 Months Compared with 6 Months Following the Implementation of Mandatory Menu Labeling Regulation in King County, Washington*, 48 Am. J. Preventative Med. 70 (2015).
[16] Sara N. Bleich et al., *Restaurants With Calories Displayed On Menus Had Lower Calorie Counts Compared To Restaurants Without Such Labels,* 34 Health Aff. 1877 (2015).
[17] Alexa Namba et al., *Exploratory Analysis of Fast-Food Chain Restaurant Menus Before and After Implementation of Local Calorie-Labeling Policies, 2005-201*1, 10 Prevention Chronic Disease E101 (2013). doi: 10.5888/pcd10.120224.

US population (children and adults) over the next 20 years ranges from $3.7 billion to $10.7 billion."[18]

44. In addition to protecting public health, nutrition labeling can reduce the environmental degradation associated with food production and disposal. Roughly 40 percent of U.S. food is wasted, and food waste decomposing in landfills releases gases that contribute to climate change.[19] A significant portion of wasted food originates at restaurants, especially those with large portion sizes.[20] By encouraging consumers to order smaller portions and restaurants to offer smaller portions, nutrition labeling contributes to closing the gap between the amount of food consumers order and the amount they eat, thereby reducing the quantity of wasted food and limiting associated environmental harm.

45. The treatment of obesity-related diseases poses a significant economic burden. Health care costs associated with adult and child obesity total $147 billion each year, and Medicare and Medicaid cover over 40 percent of the bill.[21]

II. Procedural History

46. Congress imposed the Nutrition Labeling Requirement in the ACA among other provisions to improve public health and reduce health care costs. *See* Pub. L. No. 111-148, § 4205.

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[18] FDA, FDA–2011–F–0172, Final Regulatory Impact Analysis (Nov. 2014), https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf.

[19] EPA, *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*, EPA 430-P-17-001 at 7-3 (2017), https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf; Dana Gunders, Natural Res. Def. Council, *Wasted: How America Is Losing Up to 40 Percent of Its Food from Farm to Fork to Landfill* 11 (2012), https://www.nrdc.org/sites/default/files/wasted-food-IP.pdf ("Food Waste Report").

[20] Food Waste Report at 11.

[21] Eric A. Finkelstein et al., *Annual Medical Spending Attributable To Obesity: Payer-And Service-Specific Estimates*, 28 Health Aff. w822, w829 (2009).

47. The ACA directed the FDA to promulgate proposed regulations implementing the Nutrition Labeling Requirement within one year of the ACA's enactment. *Id*. § 4205(b); *see* 21 U.S.C. § 343(q)(5)(H)(x)(I). The ACA was enacted on March 23, 2010.

48. On April 6, 2011, the FDA published a proposed rule implementing the Nutrition Labeling Requirement. 76 Fed. Reg. 19,192 (Apr. 6, 2011). Plaintiffs and many regulated entities submitted comments on this proposal.

49. On December 1, 2014, the FDA published a final rule implementing the Nutrition Labeling Requirement ("Nutrition Labeling Rule"). 79 Fed. Reg. 71,156 (Dec. 1, 2014). The Nutrition Labeling Rule had an effective date and a compliance deadline of December 1, 2015. *Id.*

50. On July 10, 2015, the FDA published a final rule extending the Nutrition Labeling Rule's compliance deadline to December 1, 2016. 80 Fed. Reg. 39,675 (July 10, 2015). The FDA granted this extension in response to requests submitted by several regulated entities working to come into compliance with the Nutrition Labeling Rule. *Id.* at 39,676. Specifically, these entities sought additional time for "developing software, information systems, and other technologies for providing nutrition information" and for "training staff, implementing standard operating procedures, and developing and installing updated and consistent menu boards across all locations within a chain." *Id*. According to the FDA, "[m]ost requests sought to extend the [Nutrition Labeling Rule's] compliance date by 1 year." *Id*. The FDA explained that granting the extension was appropriate because "allowing adequate time for covered establishments to fully implement the final rule's requirements … helps accomplish the primary objective of the [Nutrition Labeling Rule] and is in the public interest." *Id.*

51. On December 18, 2015, President Obama signed the Consolidated Appropriations

Act, 2016, Pub. L. No. 114–113. Among other requirements, this law prohibited the FDA from using appropriated funds to implement, administer, or enforce the Nutrition Labeling Rule until the later of December 1, 2016 or one year after the publication of a guidance document explaining how chain restaurants and similar retail food establishments should comply with the Nutrition Labeling Rule. *Id*. § 747.

52. On September 16, 2015, the FDA announced the availability of a draft version of the required guidance in the Federal Register. 80 Fed. Reg. 55,564 (Sep. 16, 2015). Plaintiffs and many regulated entities submitted comments on this draft.

53. On May 5, 2016, the FDA announced the availability of the final version of the required guidance in the Federal Register ("Final Nutrition Labeling Guidance"). 81 Fed. Reg. 27,067 (May 5, 2016). In this notification, the FDA indicated that the Nutrition Labeling Rule's compliance deadline had been delayed until May 5, 2017. *Id.*

54. On December 30, 2016, the FDA published a final rule "to clarify and confirm that the compliance date for the [Nutrition Labeling Rule] is May 5, 2017." 81 Fed. Reg. 96,364, 96,364 (Dec. 30, 2016).

55. On May 4, 2017, the FDA published the Delay Rule, an interim final rule delaying the Nutrition Labeling Rule's compliance date until May 7, 2018. 82 Fed. Reg. 20,825.

56. Although the Nutrition Labeling Rule's *compliance* date was delayed in July 2015, December 2015, May 2016 and, most recently, May 2017, the *effective* date of the Nutrition Labeling Rule remains December 1, 2015.

57. The FDA acknowledged that the Delay Rule would have the immediate effect of interfering with efforts being taken to achieve compliance with the Nutrition Labeling Rule. *Id*.

at 20,828. Nonetheless, the FDA did not provide the public with advance notice or an opportunity to comment on the Delay Rule before it took effect. *Id*.

58. The FDA claimed that it issued the Delay Rule "consistent with Executive Orders 13,777, 13,771, and 13,563, as well as in response to the diverse and complex set of stakeholders affected by the rule and continued, numerous, and fundamental questions they raise regarding the final rule and its implementation." 82 Fed. Reg. at 20,827. Although the Delay Rule took effect immediately, the FDA sought public comment concerning several of these "fundamental and complex questions." *Id*. In particular, the FDA indicated its "decision to reconsider the [Nutrition Labeling Rule]" and expressed interest in "approaches to reduce the [Nutrition Labeling Rule's] regulatory burden or increase flexibility with respect to: (1) Calorie disclosure signage for self-service foods, including buffets and grab-and-go foods; (2) methods for providing calorie disclosure information other than on the menu itself, including how different kinds of retailers might use different methods; and (3) criteria for distinguishing between menus and other information presented to the consumer." *Id.*

59. Executive Order 13,777 sets forth procedures "to alleviate unnecessary regulatory burdens placed on the American people." Exec. Order No. 13,777, 82 Fed. Reg. 12,285, 12,285 (Feb. 24, 2017). Executive Order 13,777 does not, and legally could not, authorize the FDA or any other agency to disregard required rule making procedures or to undertake actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

60. Executive Order 13,771 states that "it is important that for every one new regulation issued, at least two prior regulations be identified for elimination." Exec. Order 13,771, 82 Fed. Reg. 9,339, 9,339 (Jan. 30, 2017). Executive Order 13,771 does not, and legally could not, authorize the FDA or any other agency to disregard required rule making

procedures or to undertake actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

61. Executive Order 13,563 sets forth procedures "to improve regulation and regulatory review." Exec. Order 13,563, 76 Fed. Reg. 3,821, 3,821 (Jan. 18, 2011). Executive Order 13,563 does not, and legally could not, authorize the FDA or any other agency to disregard required rule making procedures or to undertake actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. To the contrary, Executive Order 13,563 reaffirms the importance of public participation in the rule making process. In fact, the FDA previously identified Executive Order 13,563 as a factor contributing to the need for the Nutrition Labeling Rule. Specifically, FDA explained that "Executive Order 13,563 specifically directs agencies to 'identify and consider regulatory approaches that … maintain flexibility and freedom of choice for the public … include[ing] … disclosure requirements as well as provision of information to the public in a from that is clear and intelligible." 76 Fed. Reg. at 19,220.

62. Contrary to the FDA's assertions in the Delay Rule, chain restaurants and similar retail food establishments have "sufficient flexibility" to implement the Nutrition Labeling Rule. 79 Fed. Reg. at 71,194 (Dec. 1, 2014) (referring to the fact that the Nutrition Labeling Rule "accommodate[s] different types of menus and menu boards and the various ways that standard menu items may be listed on menus and menu boards"). For instance, in the preamble to the Nutrition Labeling Rule, the FDA explained that restaurants and similar retail food establishments have multiple options for calculating the nutrient content of standard menu items and, therefore, the Nutrition Labeling Rule "provides flexibility for covered establishments in order to minimize costs while also helping to ensure that calorie and other nutrition information

is made available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices." *Id.* at 71,178. In addition, the Nutrition Labeling Rule "provid[es] covered establishments with the flexibility to use different types of media (*e.g.*, flyers, posters, booklets, kiosks) to provide the written nutrition information" to customers. 79 Fed. Reg. at 71,216.

63. Although the Nutrition Labeling Rule "provides flexibility where appropriate," the FDA expressly concluded that additional flexibility would conflict with specific congressional directions set forth in the ACA and undermine national uniformity in nutrition labeling, which the agency determined to be "one of the primary purposes of section 4205 of the ACA." *Id*. at 71,203.

64. The FDA has already considered approaches to calorie disclosure signage for self-service foods, including buffets and grab-and-go foods. Specifically, the Nutrition Labeling Rule permits chain restaurants and similar retail food establishments to declare the calorie contents of self-service foods by posting calories on "a sign adjacent to and clearly associated with the corresponding food," "a sign attached to a sneeze guard," or "a single sign or placard." 21 C.F.R. § 101.11(b)(2)(iii)(A). As the FDA has explained, the agency's decision to allow multiple options for compliance "provides flexibility for covered establishments." 79 Fed. Reg. at 71,179.

65. The FDA has already considered how the Nutrition Labeling Rule should apply to different kinds of retailers. For instance, in issuing the Nutrition Labeling Rule, the FDA concluded that requiring compliance by retail food establishments within entertainment venues such as movie theaters and amusement parks would "enable consumers to make informed and healthful dietary choices," thus providing an important public health benefit, while also creating

a level playing field between restaurants and similar retail food establishments. *Id.* at 71,156. The FDA also responded to multiple comments concerning the appropriate scope of entities required to comply with the Nutrition Labeling Rule and justified its decision by analyzing the specific language and legislative history of the ACA. 79 Fed. Reg. at 71,162–76.

66. The FDA has already considered criteria for distinguishing between menus and other information provided to the consumer. The Nutrition Labeling Rule defines "menu or menu board" as "the primary writing of the covered establishment from which a customer makes an order selection" sets forth multiple factors that can be used to determine whether a particular writing qualifies as a menu or menu board, including "whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing." 21 C.F.R. § 101.11(a). During the rule making process that culminated in the development of the Nutrition Labeling Rule, the FDA responded to multiple comments concerning the identification of menus and menu boards. *See* 79 Fed. Reg. at 71,176–78. Significantly, the FDA explained that the phrase "'primary writing' should be interpreted from a consumer's vantage point" and set forth multiple examples of writings that qualify as menus or menu boards. *Id.* at 71,176. The FDA's Final Nutrition Labeling Guidance further clarified the distinction between menus and advertising. *See* FDA, *A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11): Guidance for Industry* (Apr. 2016), https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf.

67. Though the Delay Rule is not a rule of procedure within the meaning of the APA, the FDA claimed that the Delay Rule "is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A)." 82 Fed. Reg. at 20,827.

68. Alternatively, and also without a legally meritorious basis for making the claim, the FDA asserted that its decision to publish the Delay Rule "without opportunity for public comment, effective immediately today upon publication in the Federal Register, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3)." *Id.* at 20,827–28. In particular, the FDA claimed that "providing an opportunity for public comment would be impracticable and contrary to the public interest," because *immediate* delay was necessary to "reduc[e] regulatory burden and costs on affected entities" and allow "affected entities [to] avoid incurring immediate costs" associated with complying with the Nutrition Labeling Rule. 82 Fed. Reg. at 20,828.

69. Because the Delay Rule was issued only one day before compliance with the Nutrition Labeling Rule was due, however, the Delay Rule will neither reduce costs to chain restaurants and similar retail food establishments nor allow these establishments to avoid incurring immediate costs associated with complying with the Nutrition Labeling Rule. In April 2017, *before* the FDA issued the Delay Rule, the agency acknowledged that, "[g]iven the imminence of the [Nutrition Labeling Rule's] current compliance date (May 5, 2017), it is likely that many covered establishments have already incurred some or all of the initial costs needed to be in compliance." FDA, Docket No. FDA-2011-F-0172, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date and Request for Comments: Interim Final Regulatory Impact Analysis; Interim Final Regulatory Flexibility Analysis; Interim Final Small Entity Analysis; Unfunded Mandates Reform Act Analysis* 7 (Apr. 2017) (referenced in the preamble to the Delay Rule and available at

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM557211.pdf). Indeed, far from welcoming this reprieve, representatives of the restaurant industry strongly oppose the FDA's decision to promulgate the Delay Rule. As a spokesperson for the National Restaurant Association explained, "[t]his delay upends plans that have been in motion for years throughout the food industry."[22]

70. According to the FDA's own calculations, the cost of the Delay Rule significantly outweighs the benefit it provides. In issuing the Delay Rule, the FDA concluded that the Delay Rule's "principal benefit … will be the reduction in costs to covered establishments associated with extending the compliance date by one year." 82 Fed. Reg. at 20,828. The FDA estimated the value of this benefit to be between $2 and $8 million, depending on the discount rate applied. In contrast, "the principal cost of [the Delay Rule] will be the reduction in benefits to consumers associated with extending the compliance date by one year." *Id.* The FDA estimated the value of this cost to be between $5 and $19 million, depending on the discount rate applied.

FIRST CLAIM FOR RELIEF

Violation of the APA: The FDA Failed to Explain its Departure from Prior Conclusions

71. The allegations set forth above are incorporated by reference.

72. The FDA adopted the Nutrition Labeling Rule pursuant to congressional mandates set forth under the ACA and FDCA, and in accordance with its authority under the APA. Pub. L. No. 111–148, § 4205; 21 U.S.C. § 343(q)(5)(H); 5 U.S.C. § 552(a)(1)(D).

73. The FDA issued the Delay Rule—thereby amending the Nutrition Labeling Rule—without rationally explaining why it was changing its interpretation of the Nutrition Labeling Requirement set forth section 4205(b) of the ACA, codified at 21 U.S.C.

[22] Helena B. Evich, *Trump's Delay of Calorie-Posting Rule Jolts Restaurants*, Politico, May 27, 2017, http://www.politico.com/story/2017/05/27/trump-restaurant-calorie-posting-rule-238873.

§ 343(q)(5)(H), or its conclusions about the importance of mandating nutrition labeling to protect public health, as articulated in the Nutrition Labeling Rule.

74. Accordingly, the Delay Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of 5 U.S.C. § 706(2)(A).

SECOND CLAIM FOR RELIEF

Violation of the APA: The FDA Failed to Comply with Mandatory Rule Making Procedures

75. The allegations set forth above are incorporated by reference.

76. The FDA issued the Delay Rule—thereby amending the Nutrition Labeling Rule—without publishing notice of proposed rule making or giving interested persons an opportunity to comment in advance, in violation of 5 U.S.C. § 553.

77. The FDA did not publish the Delay Rule 30 days before its effective date, in violation of 5 U.S.C. § 553(d).

78. The Delay Rule is not a rule of procedure under 5 U.S.C. § 553(b)(A).

79. In publishing the Delay Rule, the FDA did not have good cause under 5 U.S.C. § 553(b)(3)(B) to depart from the mandatory rule making procedures of the APA.

80. Neither did the FDA have good cause under 5 U.S.C. § 553(d)(3) to publish the Delay Rule fewer than 30 days before its effective date.

81. Accordingly, the FDA published the Delay Rule "without observance of procedure required by law," in violation of 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

For the foregoing reasons, Plaintiff respectfully requests that this Court enter an Order:

a. Declaring that the Delay Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of the APA, 5 U.S.C. §706(2)(A);

b. Declaring that the FDA promulgated the Delay Rule "without observance of procedure required by law," in violation of the APA, 5 U.S.C. § 706(2)(D);

c. Vacating the Delay Rule;

d. Declaring that compliance with the Nutrition Labeling Rule is required by a date certain, not to exceed 15 days after the Order is issued;

e. Awarding Plaintiffs attorney fees and all other reasonable expenses incurred in pursuit of this action; and,

f. Granting other such injunctive and/or declaratory relief as the Court deems necessary, just and proper.

Respectfully submitted this 7th day of June 2017.

/s/ Seth L. Johnson_____
Seth L. Johnson
D.C. Bar No. 1001654
Earthjustice
1625 Massachusetts Avenue, N.W., Suite 702
Washington, D.C. 20036
T: (202) 667-4500
E: sjohnson@earthjustice.org

Peter Lehner*
Alexis Andiman*
Earthjustice
48 Wall Street, 19th Floor
New York, NY 10005
T: (212) 845-7376
E: plehner@earthjustice.org
aandiman@earthjustice.org

Counsel for Plaintiffs

* Application for admission *pro hac vice* pending.

Exhibit A

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a determination that undetected web fatigue cracking caused by oil canning may exist in the station 1440 aft pressure bulkhead web. We are issuing this AD to detect and correct fatigue cracking of the aft pressure bulkhead web, which could grow in length and ultimately reduce the structural integrity of the web and lead to rapid decompression of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections and Related Investigative and Corrective Actions

At the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016, except as required by paragraph (h)(1) of this AD: Do all applicable actions specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016, except as required by paragraph (h)(2) of this AD.

(1) Do a detailed inspection of the station 1440 aft pressure bulkhead web for any oil canning. Repeat the inspection at the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016.

(2) Do all applicable related investigative actions, including detailed, eddy current, and high frequency eddy current (HFEC) inspections. Repeat the applicable inspections thereafter at the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016.

(3) Do all applicable corrective actions at the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016.

(h) Service Information Exceptions

(1) Where Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016, specifies a compliance time "after the original issue date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016, specifies to contact Boeing for repair instructions, and specifies that action as Required for Compliance (RC), this AD requires repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Special Flight Permit

Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the airplane can be repaired, but if any crack is found as identified in Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016, concurrence by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, is required before issuance of the special flight permit.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled "RC Exempt," then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

For more information about this AD, contact George Garrido, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5232; fax: 562–627–5210; email: *george.garrido@faa.gov*.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing 707 Alert Service Bulletin A3543, dated September 15, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; Internet *https://www.myboeingfleet.com*.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Renton, Washington, on April 24, 2017.

Paul Bernado,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–08828 Filed 5–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

RIN 0910–ZA48

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; extension of compliance date; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. In the **Federal Register** of December 30, 2016, we stated that the compliance date for the final rule would be May 5, 2017. We are extending the compliance date to May 7, 2018. We are taking this action to enable us to consider how we might further reduce the regulatory burden or increase

flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration's policies.

DATES: *Compliance date:* As of May 4, 2017, the compliance date for covered establishments set out in the final rule published December 1, 2014 (79 FR 71156), and extended in final rules published on July 10, 2015 (80 FR 39675) and December 30, 2016 (81 FR 96364), is further extended. Covered establishments must comply with the rule published December 1, 2014 (79 FR 71156), by May 7, 2018.

Comment date: Submit either electronic or written comments regarding this compliance date extension, implementation of the December 2014 final rule, and the various topics flagged in the **SUPPLEMENTARY INFORMATION** section of this document, by July 3, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 3, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2011–F–0172 for "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments." Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule, which is now codified at § 101.11 (21 CFR 101.11), implements provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) and:

- Defines terms, including terms that describe criteria for determining whether an establishment is subject to the rule;
- establishes which foods are subject to the nutrition labeling requirements and which foods are not subject to these requirements;
- requires that calories for standard menu items be declared on menus and menu boards that list such foods for sale;
- requires that calories for standard menu items that are self-service or on display be declared on signs adjacent to such foods;
- requires that written nutrition information for standard menu items be available to consumers who ask to see it;
- requires, on menus and menu boards, a succinct statement concerning suggested daily caloric intake (succinct statement), designed to help the public understand the significance of the calorie declarations;
- requires, on menus and menu boards, a statement regarding the availability of the written nutrition information (statement of availability);
- establishes requirements for determination of nutrient content of standard menu items;
- establishes requirements for substantiation of nutrient content

determined for standard menu items, including requirements for records that a covered establishment must make available to FDA within a reasonable period of time upon request; and

- establishes terms and conditions under which restaurants and similar retail food establishments not otherwise subject to the rule could elect to be subject to the requirements by registering with FDA.

In the preamble to the final rule (79 FR 71156 at 71239 through 71241), we stated that the rule would be effective on December 1, 2015, and also provided a compliance date of December 1, 2015, for covered establishments. The final rule (at § 101.11(a)) defines "covered establishment" as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.*, individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is voluntarily registered to be covered under § 101.11(d).

II. Extension of the Compliance Date and Request for Comments

In the **Federal Register** of July 10, 2015 (80 FR 39675), in response to requests from affected entities, we announced our decision to extend the compliance date for the final rule to December 1, 2016.

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 747 of that law states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the final rule entitled "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" until the later of December 1, 2016 or 1 year after the date we publish a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments.

In the **Federal Register** of May 5, 2016 (81 FR 27067), we announced the availability of the Level 1 guidance document and stated that enforcement of the final rule published December 1, 2014, would commence on May 5, 2017 (81 FR 27067 at 27068). In the **Federal Register** of December 30, 2016 (81 FR 96364), we confirmed that the compliance date would be May 5, 2017.

This interim final rule extends the compliance date to May 7, 2018. We are taking this action consistent with Executive Orders 13777, 13771, and 13563, as well as in response to the diverse and complex set of stakeholders affected by the rule and continued, numerous, and fundamental questions they raise regarding the final rule and its implementation. The continued, fundamental questions and concerns with the final rule suggest that critical implementation issues, including some related to scope, may not have been fully understood and the agency does not want to proceed if we do not have all of the relevant facts on these matters. Retailers with many different and diverse business models have raised concerns about how the rule lacks flexibility to permit them to provide meaningful nutrition information to consumers given their type of business and different operations. Moreover, we continue to receive many questions about calorie disclosure signage for self-service foods, including buffets and grab-and-go foods. We do not want to proceed with a rule that might turn out to be too inflexible to support innovation in delivering information to consumers. In addition, we have received questions regarding how to distinguish a menu, which requires the posting of calorie information, from advertisements and other marketing pieces, which do not require calorie information. Many of these menu questions are complex and have highlighted for the agency the need for further consideration and clarification. How to address the natural calorie variations for foods has also been raised by stakeholders as an issue that needs additional guidance and clarity. Finally, some entities with certain business models have stated that they continue to have questions about what provisions of the final rule are applicable to them. We believe questions like this still need to be addressed.

The previous extensions, as well as Congressional concern regarding implementation expressed through letters and appropriations law, are a reflection of the challenge in implementing this rule for a diverse industry of approximately 298,600 covered establishments, organized under 2,130 chains, that we estimated to be covered by the 2014 final rule. Executive Order 13777, "Enforcing the Regulatory Reform Agenda" (82 FR 12285, March 1, 2017), sets forth a policy to alleviate unnecessary regulatory burdens. Given the principles and policies set forth in these executive orders, particularly with respect to reducing burdens, reducing costs, maintaining flexibility, and improving effectiveness, we have decided to extend the compliance date to May 7, 2018. The additional time will allow us to consider what opportunities there may be to address these fundamental and complex questions and reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule. Given our decision to reconsider the rule consistent with these Executive Orders, it would not make sense to require establishments covered by our final rule to come into compliance with the rule (for which compliance is not yet required), as well as incur additional ongoing costs to maintain or update compliance, when these requirements may change as a result of our reconsideration of the rule. We solicit comment on the extension of the compliance date.

To assist us in our review, we invite interested parties to submit comments on how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives to provide consumers with nutrition information so that they can make informed choices for themselves and their families. In particular, and in light of the issues we have noted above, we are interested in hearing about approaches to reduce the regulatory burden or increase flexibility with respect to:

(1) Calorie disclosure signage for self-service foods, including buffets and grab-and-go foods;

(2) methods for providing calorie disclosure information other than on the menu itself, including how different kinds of retailers might use different methods; and

(3) criteria for distinguishing between menus and other information presented to the consumer. (See **ADDRESSES** for instructions on submitting comments.) These questions have been identified by stakeholders as among the fundamental issues that continue to pose significant implementation challenges. As of April 7, 2017, we have received five requests for an extension of the compliance period, which we will add to the docket. In addition, on April 5, 2017, a request to stay the effective date was submitted to FDA (see Docket No. FDA–2017–P–2164); this request is currently under consideration.

To the extent that 5 U.S.C. 553 applies to this extension of the compliance date, the action is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, to the extent that the notice-and-comment and delayed effective date requirements set forth in 5 U.S.C. 553 applies to this action, the implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register,** is based

on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Given the imminence of the compliance date (May 5, 2017), and the fact that, as discussed above, a number of regulated establishments continue to raise numerous, complex questions about applicability of the menu labeling requirements and about how to implement them, we have decided that providing an opportunity for public comment would be impracticable and contrary to the public interest. This is because providing immediate notice to covered establishments of the additional time to come into compliance allows for more efficient planning and accounting for implementation of requirements, thus reducing regulatory burden and costs on affected entities. In addition, providing immediate notice that there will be additional time to comply is necessary so that affected entities can avoid incurring immediate costs and efficiently plan and account for implementation of the requirements by the imminent compliance date. Good cause exists to delay the compliance date without comment and effective immediately. In accordance with 21 CFR 10.40(e)(1), however, we note that interested parties may provide comment on the compliance date extension, including whether it should be modified or revoked. In addition, interested parties may submit comments on how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives with respect to providing consumers with nutrition information so that they can make informed choices for themselves and their families. In addition, as we have done throughout this complex rulemaking process, we will continue to work with stakeholders as we go forward.

III. Economic Analysis of Impacts

We have examined the impacts of the interim final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with new regulations shall "be offset by the elimination of existing costs associated with at least two prior regulations." We have developed an Economic Analysis of Impacts that assesses the impacts of the interim final rule, including cost savings to industry and foregone benefits to consumers. We estimate at least one type of impact in at least one year to be greater than $100 million. Thus, we believe that this interim final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule reduces the burden on covered establishments by further extending the compliance date for the "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" final rule (79 FR 71156, December 1, 2014 (final rule); 80 FR 39675, July 10, 2015 (extending the compliance date to December 1, 2016); 81 FR 96364, December 30, 2016 (clarifying extension of the compliance date to May 5, 2017)), we certify the interim final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This interim final rule would not result in an expenditure by industry in any year that meets or exceeds this amount.

This interim final rule extends the compliance date to May 7, 2018, for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and similar retail food establishments. The principal benefit of this interim final rule will be the reduction in costs to covered establishments associated with extending the compliance date by one year. The total annualized benefit (*i.e.*, cost savings) of this interim final rule, using a 3-percent discount rate over 20 years, would be from $2 to $6 million; with a 7-percent discount rate, the annualized benefit would be $3 to $8 million. The principal cost of this interim final rule will be the reduction in benefits to consumers associated with extending the compliance date by one year. The total annualized cost (*i.e.*, foregone benefits) of this interim final rule, using a 3-percent discount rate over 20 years, would be from $5 to $15 million; with a 7-percent discount rate, the annualized cost would be $6 to $19 million. Extending the compliance date of the "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" final rule by one year reduces the annualized net benefits (discounted at 3 percent) approximately 1 percent, from $506 million to $501 million. While average annualized net benefits decrease by $5 million, they are still positive. We recognize that there may be additional costs and benefits to both consumers and covered establishments that we do not have the data to quantify here. We are presenting the estimated benefits and costs of the menu labeling final rule, which takes effect according to the dates in this interim final rule. These quantitative estimates reflect an assumed baseline in which the menu labeling regulation eventually goes fully into effect. If statutory or other changes that are separate from FDA rulemaking were to impact full implementation, the quantitative benefits estimates would be lower and the quantitative cost estimates higher than shown here. We invite comment on both this Regulatory Impact Analysis and the Regulatory Impact Analysis for the December 2014 final rule.

The full analysis of economic impacts is available in the docket for this interim final rule (Ref. 1) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IV. Paperwork Reduction Act

This interim final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Reference

The following reference is on display in the Division of Dockets Management (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.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register,** but Web sites are subject to change over time.

1. FDA, interim economic impact analysis for "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comment," April 2017. Available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

Dated: May 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09029 Filed 5–1–17; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA–2016–F–1805]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned. This action is in response to a petition filed by Keller and Heckman LLP on behalf of the Society of the Plastics Industry, Inc.

DATES: This rule is effective May 4, 2017. Submit either electronic or written objections and requests for a hearing on the final rule by June 5, 2017. See the **ADDRESSES** section, and **SUPPLEMENTARY INFORMATION** section VIII of this document, for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before June 5, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 5, 2017. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–F–1805 for "Indirect Food Additives: Polymers." Received objections, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian Gilliam, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1193.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of June 30, 2016 (81 FR 42585), we announced that we filed a food additive petition (FAP 6B4816) submitted on behalf of Society of the Plastics Industry, Inc. (SPI) by Keller and Heckman LLP, 1001 G Street NW., Suite 500 West, Washington, DC 20001. The petition proposed to amend § 177.1210 (21 CFR 177.1210) to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because the use has been intentionally and permanently abandoned.