Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area

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ANM ID E4 Pocatello, ID [Removed]

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth

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ANM ID E5 Pocatello, ID [Amended]

Pocatello Regional Airport, ID
(Lat. 42°54′35″ N, long. 112°35′45″ W)

That airspace extending upward from 700 feet above the surface within 7.8 miles northwest and 5 miles southeast of the 045° bearing from Pocatello Regional Airport extending to 21 miles northeast of the airport, and within 7.8 miles northwest and 5 miles southeast of the 225° bearing from the airport extending to 10.8 miles southwest of the airport. That airspace extending upward from 1,200 feet above the surface within 15 miles northwest and 5 miles southeast of the 045° bearing from Pocatello Regional Airport extending to 43 miles northeast of the airport, and within 15 miles northwest and 5 miles southeast of the 225° bearing from the airport extending to 15 miles southwest of the airport.

Issued in Seattle, Washington, on April 23, 2018.

B. G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–09107 Filed 5–3–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. FDA–2012–N–1210 and FDA–2004–N–0258]

RIN 0910–AH92

Food Labeling: Revision of the Nutrition and Supplement Facts Labels and 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; Extension of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance dates by approximately 1.5 years for the final rules providing updated nutrition information on the label of food, including dietary supplements; defining a single-serving container; requiring dual-column labeling for certain containers; updating, modifying, and establishing certain reference amounts customarily consumed (RACCs); and amending the label serving size for breath mints. The final rules appeared in the **Federal Register** of May 27, 2016. We are taking this action because, after careful consideration, we have determined that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules, and that they have sufficient time to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the final rules.

DATES: This rule is effective July 3, 2018. For the applicable compliance date(s), please see ''Effective/Compliance Date(s)'' in **SUPPLEMENTARY INFORMATION.**

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2579.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

The final rule extends the compliance dates for two rules. In the **Federal Register** of May 27, 2016 (81 FR 33742 and 81 FR 34000), we published two final rules entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (the Nutrition Facts Label Final Rule) and ''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'' (the Serving Size Final Rule). In those final rules the compliance date for manufacturers with $10 million or more in annual food sales was established as July 26, 2018; for manufacturers with less than $10 million in annual food sales, the compliance date was set as July 26, 2019.

This final rule extends the compliance date for manufacturers with $10 million or more in annual food sales from July 26, 2018, to January 1, 2020; for manufacturers with less than $10 million in annual food sales, the final rule extends the compliance date from July 26, 2019, to January 1, 2021.

B. Summary of the Final Rule

The final rule extends the compliance date for manufacturers with $10 million or more in annual food sales from July 26, 2018, to January 1, 2020; for manufacturers with less than $10 million in annual food sales, the final rule extends the compliance date from July 26, 2019, to January 1, 2021. We are extending the compliance dates for the Nutrition Facts Label Final Rule and the Serving Size Final Rule, which were issued consistent with our authority in sections 403(q), 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q), 343(a)(1), 321(n), and 371(a), respectively) and section 2(b)(1) of the Nutrition Labeling and Education Act (NLEA) (Pub. L. 101–535).

C. Costs and Benefits

The impact of this final rule is summarized in the following table.

TABLE 1—SUMMARY OF THE COST SAVINGS TO INDUSTRY AND FOREGONE BENEFITS TO CONSUMERS OF THIS FINAL RULE TO EXTEND THE COMPLIANCE DATES

[In billions of 2016$]

	Discount rate	Cost savings	Foregone benefits	Net benefits (cost savings—foregone benefits)
Present Value	3	$1.0	$0.9	$0.1
	7	1.0	0.9	0.1
Annualized Amount	3	0.07	0.06	0.01
	7	0.09	0.08	0.01

Notes: Cost savings to industry, foregone benefits to consumers, and net benefits reflect mean estimates. This final rule extends the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

II. Background

A. Need for the Regulation/History of This Rulemaking

In the **Federal Register** of May 27, 2016 (81 FR 33742 and 81 FR 34000), we published the Nutrition Facts Label Final Rule and the Serving Size Final Rule. The Nutrition Facts Label Final Rule revises the Nutrition Facts label by:

- Removing the declaration of ''Calories from fat'' because current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases;
- Requiring the declaration of the gram amount of ''Added Sugars'' in a serving of a product, establishing a Daily Reference Value (DRV), and requiring the percent Daily Value (DV) declaration for added sugars;
- Changing ''Sugars'' to ''Total Sugars'' and requiring that ''Includes 'X' g Added Sugars'' be indented and declared directly below ''Total Sugars'' on the label;
- Updating the list of vitamins and minerals of public health significance. For example, the Nutrition Facts Label Final Rule requires the declaration of vitamin D and potassium and permits, rather than requires, the declaration of vitamins A and C;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts label to increase the prominence of both the term ''Calories'' and the calories information;
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets; and
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances.

The Serving Size Final Rule requires all containers, including containers of products with ''large'' RACCs (*i.e.,* products with RACCs of at least 100 grams (g) or 100 milliliters (mL)), containing less than 200 percent of the RACC to be labeled as a single-serving container. Except for when certain exceptions apply, the Serving Size Final Rule further requires that containers and units that contain at least 200 percent and up to and including 300 percent of the RACC be labeled with a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container or unit, as applicable, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container or unit, as applicable (*i.e.,* the serving size derived from the RACC). The Serving Size Final Rule also updates, modifies, and establishes RACCs for certain foods and product categories.

The Final Rules established compliance dates for manufacturers with $10 million or more in annual food sales of July 26, 2018, and for manufacturers with less than $10 million in annual food sales, of July 26, 2019.

After we published the Nutrition Facts Label and the Serving Size Final Rules, companies and trade associations with members covered by the rules informed us that they had significant concerns about their ability to update all their labels by the compliance dates due to issues regarding (among other things) the need for upgrades to labeling software, the need to obtain nutrition information from suppliers, the number of products that would need new labels, and a limited time for reformulation of products. Consequently, in the **Federal Register** of October 2, 2017 (82 FR 45753), we proposed to extend the compliance dates to provide more time to comply with the Nutrition Facts Label and the Serving Size Final Rules. We proposed extending the compliance dates by approximately 1.5 years for both categories of manufacturers as a means to balance the importance of ensuring that industry has sufficient time to comply with the new requirements, and the importance of decreasing costs, against the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 30-day comment period. We received approximately 50,000 comments. The comments came from individual consumers, consumer groups, industry, trade associations, academia, health professionals, and state/local government Agencies. Some comments sought an even longer extension of the compliance dates or said a compliance date should be aligned with the United States Department of Agriculture's (USDA) work to implement the National Bioengineered Food Disclosure Law. Comments opposing an extension (including those from state or local government Agencies) focused, in large part, on the Nutrition Facts label's role in helping consumers maintain a healthy lifestyle, possible consumer confusion if two versions of the Nutrition Facts label exist in the market, and a belief that firms had adequate time to comply. Comments supporting an extension of the compliance dates stressed that companies need additional time to update their labels. For example, some comments stressed that the process for relabeling may involve coordination between a variety of parties to test and analyze products, enter ingredient information into databases, develop new labels, and print

new labels. According to these comments, having more time to comply with the Nutrition Facts Label and the Serving Size Final Rules will help ensure the accuracy of the labels and will allow for consistent application and fuller compliance across industry.

C. Overview of the Final Rule

The final rule extends the compliance date for the Nutrition Facts Label Final Rule and the Serving Size Final Rule for manufacturers with $10 million or more in annual food sales from July 26, 2018, to January 1, 2020; for manufacturers with less than $10 million in annual food sales, the final rule extends the compliance date from July 26, 2019, to January 1, 2021. The Nutrition Facts Label Final Rule and Serving Size Final Rule were issued consistent with our authority in sections 403(q), 403(a)(1), 201(n), and 701(a) of the FD&C Act and section 2(b)(1) of the NLEA.

III. Comments on the Proposed Rule and FDA Response

We have numbered each comment to help distinguish among different comments. We have grouped similar comments together under the same number, and in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

A. Comments Supporting or Opposing the Extension of Compliance Dates

(Comment 1) Many comments expressed concern that extending the compliance dates will delay the health and dietary benefits of the final rules because, for the period of the extension, the public would be precluded from making informed food choices based on the updated scientific information. Some comments expressed concern about the impact of the delay on people with certain medical conditions (such as cancer, diabetes, heart disease, high blood pressure, and obesity), stating that such people might be better able to follow medical advice using the new labels. The comments further stated that the extension means that until the new compliance dates consumers will not be able to follow advice in the 2015–2020 Dietary Guidelines for Americans and advice from other public health authorities on issues not reflected in the current Nutrition Facts label, such as limiting added sugar. Some comments asserted that consumers have a ''right to know'' what is in the product. Some comments also noted that the new labels are easier to understand and use for comparing products and making healthier choices.

(Response) Both the old and new versions of the Nutrition Facts label provide information that must be truthful and accurate. While we agree that extending the compliance dates will mean that certain information required on the new Nutrition Facts label under the Nutrition Facts and Serving Size Final Rules will not be available to consumers on all foods as soon as originally anticipated, consumers can still use the old Nutrition Facts label to help guide them in their food choices in the interim. Consumers with medical conditions should continue to follow the advice they receive from a health care professional concerning their conditions.

Although we are extending the compliance dates, this extension does not prevent companies from revising their labels before the new compliance dates. In fact, according to food labeling data from Label Insight, over 29,000 products have adopted the new Nutrition Facts label (Ref. 2).

(Comment 2) Some comments stated that having both the old and new versions of the Nutrition Facts labels in the marketplace will confuse consumers and hinder their ability to compare products. The comments stated that extending the compliance dates will increase the transition period from old to new versions of the Nutrition Facts label.

Some comments asserted that providing nutrition education is difficult when two versions of the Nutrition Facts label are in the marketplace. The comments also noted that the existence of old versions of the Nutrition Facts label on food packages delays the ability to teach people to make informed choices about their health.

A comment supporting an extension of the compliance dates asserted that, from a foreign food manufacturer's perspective, the extension of the compliance dates is greatly appreciated because foreign manufacturers tend to have longer revision cycles for food packaging destined for the United States; the comment said that a longer transitional period will allow foreign firms to take more time in ''picking the right look'' for their U.S. products.

A comment supporting the extension of the compliance dates stated that, during the transition, FDA should work to ensure that consumers are aware of and educated about the importance of the changes. Some comments noted that the extension will allow FDA and stakeholders more time to prepare consumer education efforts and to raise awareness.

(Response) We recognize that there will be a longer transition period when the two Nutrition Facts labels are in the marketplace. We also note that both labels must provide information that is truthful and accurate. To help consumers during the transition, we will be providing educational materials to help consumers understand information on the labels. Many nutrition education messages will remain similar for both labels (*e.g.,* awareness of calories, serving size information, and using the daily values); for the new information for consumers (*e.g.,* added sugars, potassium, vitamin D, and dual-column labeling) we will be updating education material, especially as the new label is becoming more common in the marketplace. We are working with other Federal government Agencies (including other Agencies within the Department of Health and Human Services), health professional organizations, food manufacturers, retailers, and non-profit organizations with an interest and focus on nutrition education and health promotion to develop and disseminate our educational materials on the new Nutrition Facts label.

Furthermore, we are continuing a variety of activities, such as conducting and reporting on food labeling research. We plan to continue to build partnerships to develop, disseminate, and evaluate labeling education efforts that target specific groups, including low literacy consumers and sub-populations at high risk of nutrition-related chronic disease, in addition to the general public.

(Comment 3) Several comments stated that companies have had sufficient time and resources to comply with the original compliance dates and that compliance by some companies shows that the original compliance dates can be met. The comments also pointed out that companies regularly change their packaging. The comments urged us not to be persuaded by industry to delay the compliance dates, stated that we provided no evidence to support industry's claims for the need for additional time, and expressed concerns that companies will use the delay to challenge the final rules. Another comment claimed that large companies are capable of developing new labels, but seek to extend the compliance date so that they can reformulate their products to remove or change ingredients or information before they

have to declare those ingredients or information in a new Nutrition Facts label. Some comments also questioned whether extending the compliance dates would be fair to firms that have revised their Nutrition Facts labels already. One comment said that businesses that take advantage of an extended compliance date may have an unfair market advantage because of consumer familiarity with the old label, while another comment asserted that businesses that delay compliance with the new requirements might gain an advantage from consumers that may select a food based on the old label that they might not select based on the new label. Another comment stated that we should not extend the compliance dates and instead suggested rewarding companies that revised their Nutrition Facts labels in the original timeframe and penalizing companies that failed to revise their labels within a specific time period.

Many other comments supported the extension of the compliance dates. Some comments supporting an extension of the compliance dates stated that companies need additional time to update their labels. For example, some comments stated that some products may need to be reformulated and the process for relabeling may involve coordination between a variety of parties to test and analyze products, enter ingredient information into databases, develop new labels, and print new labels. Additionally, some comments stated that printing companies complete the orders of larger companies or packing orders before completing the orders of small and mid-size companies, that the range of label changes necessitates additional time, and that products with more ingredients take longer to relabel. According to the comments, having more time will help ensure the accuracy of the labels and will allow for consistent application and fuller compliance across industry. Furthermore, some comments noted that additional time for compliance once FDA makes decisions regarding the citizen petitions for dietary fiber would help ensure that consumers have access to products that help to meet their dietary fiber needs.

One comment suggested that we pause the compliance dates pending publication of the guidance documents or consider granting an additional extension in the future based on finalization of the guidance documents and future stakeholder concerns. Other comments suggested that we exercise enforcement discretion in cases where awaiting the guidance prevents companies from timely compliance with the original compliance dates. Some comments suggested that we base the dates on publication of the guidance documents, allowing firms additional time to implement the changes.

(Response) We have carefully considered the comments supporting and opposing an extension of the compliance dates, and we are extending the compliance dates to allow manufacturers additional time to comply with the final rules. We are aware that a number of manufacturers are already using labels consistent with the new requirements; however, we also are aware that other manufacturers have explained why the original compliance dates would not be feasible. We note that manufacturers will need to change different parts of their labels depending on the products they make.

The comments stating that an extension of the compliance dates is not warranted because some members of industry have already adopted the new labels did not explain why the fact that some manufacturers have had sufficient time to adopt the new labels means that all members of industry have had sufficient time to adopt the new labels. Based on the information available to FDA and the information provided by industry commenters, we understand that manufacturers' ability to meet the original compliance date is affected by many factors and that not all manufacturers are able to meet the original date.

Extending the compliance dates by approximately 1.5 years is guided by the desire to give industry more time, balanced against minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace. The compliance date is the date by which we expect firms to be in compliance with a specific regulatory requirement. It would be prudent for companies to take actions (such as working with suppliers to make sure they have the information they need to update their labels, redesigning labels, and printing new labels, if necessary) to meet their regulatory obligations when the compliance date is reached.

With respect to comments that suggested factoring in when FDA issues guidance documents, we note that, in the **Federal Register** of March 2, 2018, we announced the availability of final guidance documents for industry entitled ''Reference Amounts Customarily Consumed: List of Products for Each Product Category'' and ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30).'' We issued these guidance documents to address questions we received after we issued the final rules in order to address such questions and help firms with their decisions about how to comply with a particular requirement or what information to submit to FDA in a citizen petition to request a non-digestible carbohydrate be included in the definition of ''dietary fiber.''

With regard to the unfair market advantage issue raised in the comments, we have no data or information to show whether companies that have revised their Nutrition Facts labels already have an unfair market advantage or, conversely, are disadvantaged compared to companies that have not revised their Nutrition Facts labels yet. Therefore, we decline to speculate on whether an unfair market advantage exists and for the reason the comment asserted.

Finally, with regard to rewarding companies that revised their Nutrition Facts labels in the original timeframe and penalizing companies that failed to revise their labels within a specific time period, the comment provided no recommendation for how such a reward or penalty system could work or how such system would be implemented consistent with our existing authorities.

(Comment 4) Several comments would have us align the compliance dates with the National Bioengineered Food Disclosure Standard (which is administered by USDA). Other comments supported a coordinated, uniform label compliance dates across agencies because, according to the comments, USDA's Food Safety and Inspection Service also has Nutrition Facts label requirements for meat and poultry. In addition, other comments urged us to finalize other pending labeling changes (such as vending machine labeling, ''natural'' labeling, revising the definition of ''healthy,'' and ''gluten-free'' for fermented or hydrolyzed food products) before the extended compliance dates.

(Response) FDA and USDA collaborate to align compliance dates of regulations that require changes in food labeling. FDA is working to address, as appropriate and as time and resources permit, other regulatory issues that are outside the scope of this rulemaking in separate rulemaking actions. However, we do not agree that we need to ensure the alignment of compliance dates for other regulatory initiatives with those for the Nutrition Facts Label and Serving Size Final Rules.

(Comment 5) Several comments suggested alternatives to basing the compliance dates on the amount of annual sales. One comment suggested

having just one extended compliance date to show impartiality and hold all businesses to the same standards, and some comments suggested other timeframes for the compliance dates. One comment would allow extensions on a case-by-case basis rather than a blanket extension. One comment suggested basing the date on the number of products sold as companies with more products may need more time to relabel, regardless of their total sales, than companies with fewer products. One comment would support extending the compliance date for small manufacturers only; the comment said that larger manufacturers (with over $10 million in annual food sales) do not need an extension because they have greater access to scientific information about their products as well as nutritional information compared to smaller companies. One comment suggested limiting the extension to honey products and products that contain fiber and not extending the compliance dates for all other products because, the comment stated, issues pertaining to added sugars in honey and the definition of fiber must be resolved before we establish compliance dates for honey products and products that contain fiber.

Other comments suggested that we stagger the compliance dates based on the type of business. According to the comments, ingredient manufacturers would comply first with finished goods manufacturers complying at least 1 year later. The comments indicated that providers of nutrition analysis and manufacturers of finished products need the information from ingredient manufacturers to relabel their products. One comment said extending the compliance dates may cause suppliers to delay revising their Nutrition Facts label, which would prohibit a company from keeping its existing timeline for label updates and could require the company to invest in off-cycle printing fees of old nutrition labels, leading to higher costs and compromising the ability to provide complete nutrition information on customer facing labels.

(Response) In the Nutrition Facts Label and Serving Size proposed rules (79 FR 11879 and 79 FR 11989; March 3, 2014), we originally proposed one compliance date of 2 years after the effective date, regardless of annual amount of sales. However, comments to the proposed rule for the Nutrition Facts Label suggested that small businesses may need more time or may face different challenges, compared to large businesses, in complying with the final rules. Because the comments emphasized the rules' potential impact on small businesses, we agreed that the impacts to smaller businesses may be more substantial than those on larger businesses, and so we provided a 3-year compliance date for manufacturers with less than $10 million in annual food sales. Thus, in the final Nutrition Facts label and Serving Size rules, the compliance date for manufacturers with $10 million or more in annual food sales was set at July 26, 2018; the compliance date for manufacturers with less than $10 million in annual food sales was set at July 26, 2019.

Regarding the comments suggesting alternative timeframes for compliance and comments suggesting alternative approaches to extended compliance dates (such as basing the dates on the number of products sold or having ingredient suppliers comply before other entities), the comments did not provide information that would enable us, as part of this rulemaking, to revise or alter our approach. For example, the comments did not explain what total number of products sold would be used as a basis for setting compliance dates.

With respect to ingredient suppliers, we note that bulk ingredient suppliers are not required to comply with the Nutrition Facts label requirements unless, among other requirements, the bulk ingredients are going directly to the consumer (see 21 CFR 101.9(j)(9)). Furthermore, as stated in our responses to comments 1 and 3, an extension of the compliance dates does not prevent manufacturers from revising their Nutrition Facts labels before the extended compliance dates.

Based on the comments received regarding the processes involved in obtaining nutrient information from suppliers and timing involved for various size businesses to gain access to equipment for developing and printing new labels, we consider the extended compliance dates in this final rule to provide adequate time for the coordination between suppliers, manufacturers, and labelers to ensure that new labels are ready and in use by the compliance dates.

(Comment 6) Some comments opposing the extension of the compliance dates asserted that the need for guidance is not a reason to delay the compliance dates because guidance documents are only recommendations and not enforceable. In contrast, comments supporting an extension of the compliance dates said that companies need guidance from FDA to address technical questions on issues such as dietary fiber, added sugars, serving sizes, small package labeling, and allulose before they can relabel and reformulate certain products. Some comments asserted that if food companies and manufacturers are given time to comply with the rules after they receive guidance from FDA, they would not need to make additional label changes. Other comments urged us to issue guidance documents as soon as possible, and some comments asserted that we need to publish the final guidance documents on dietary fiber and added sugars before we finalize a rule regarding the compliance dates.

(Response) After careful consideration, we have determined that extending the compliance dates by approximately 1.5 years, until January 1, 2020, or January 1, 2021 (depending on annual sales), would help ensure that all manufacturers covered by the final rules have time to use guidance from FDA to address, for example, certain technical questions we received after publication of the final rules. To the extent we issue a guidance document on a specific topic in advance of the applicable compliance date, we intend to issue such guidance document in draft form with an opportunity for public comment and, where appropriate, to finalize the guidance before those parties are expected to comply with the final rules. Additional time will also help to ensure that manufacturers have time to coordinate with various parties to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the final rules.

With regard to the comments about the enforceability of guidance, we agree that our guidance documents do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. Furthermore, as we stated in our response to comment 3, in the **Federal Register** of March 2, 2018, we announced the availability of final guidance documents for industry entitled ''Reference Amounts Customarily Consumed: List of Products for Each Product Category'' (83 FR 9000) (Ref. 3) and ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)'' (83 FR 8997) (Ref. 4). In addition to the final guidance documents, in the **Federal Register** of January 5, 2017, we announced the availability of draft guidance to address issues related to added sugars entitled, ''Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added

Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals. '' Further, in the **Federal Register** of March 2, 2018, we announced the availability of draft guidance entitled ''The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products '' (83 FR 8953) (Ref. 5). We issued these guidance documents to address questions we received after we issued the final rules, and these guidance documents should address the questions and help firms with their decisions about how to comply with particular requirements such as serving sizes or the declaration of added sugars or what information to submit to FDA in a citizen petition to request a non-digestible carbohydrate be included in the definition of ''dietary fiber.''

(Comment 7) One comment stated that giving large food manufacturers an additional 18 months to conform seems excessive. The comment noted that, to satisfy the requirement under 5 U.S.C. 553 (the section of the Administrative Procedure Act (APA) pertaining to rulemaking), the notice of proposed rulemaking should include all relevant studies and data used to make the rule. The comment requested additional information regarding the complexity of the burdens being placed on food manufacturers to support an extension of the compliance dates. The comment said that such information is necessary to satisfy the requirement under 5 U.S.C. 553 that the notice of proposed rulemaking include all relevant studies and data used to make the rule. The comment cited *American Radio Relay League, Inc.* v. *Fed. Communications Comm.* 524 F.3d 227 (D.C. Cir. 2007).

Another comment expressed concern that the extension of the compliance dates may violate the APA. The comment said that the proposed rule did not ask for comments relating to breath mints and did not refer to what a reformulation of products would look like or why a reformulation is necessary.

(Response) We believe that we have provided an adequate basis for the extension of the compliance dates. Thus, we disagree that the APA requires us to provide information, in addition to what we have already made available in the public docket for notice and comment, to support the extension of the compliance dates. In addition, the case the comment relies on concerns a situation where an agency engaged in rulemaking failed to make information on which it relied publicly available for notice and comment (*American Radio Relay League,* 524 F.3d at 237 through 239). The information on which we rely in this final rule to extend the compliance dates for the Nutrition Facts Label Final Rule and the Serving Size Final Rule, in contrast, was made publicly available for comment in the public docket for the proposed rule, which is the same docket as this final rule. We are not withholding information from the public docket on which we rely for our decision to extend the compliance dates.

As discussed in the preamble to the proposed rule to extend the compliance dates for the Nutrition Facts Label and Serving Size Final Rules (82 FR 45753 at 45754), we are taking this action because, after careful consideration, we have determined that additional time would help ensure that all manufacturers covered by the rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules. We also are taking this action so that manufacturers may complete all the necessary steps and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the rules. Companies and trade associations have informed us that they have significant concerns about their ability to update all their labels by the original compliance dates due to issues regarding (among other things) the need for upgrades to labeling software, the need to obtain nutrition information from suppliers, the number of products that would need new labels, and a limited time for reformulation of products (82 FR 45753 at 45754). Comments in response to the proposed rules reiterated the basis for the requests for additional time. Based on the information in the public docket, we have a sufficient basis on which to extend the compliance dates for the final rules.

In addition, as discussed in the Preliminary Regulatory Impact Analysis referenced in the proposed rule to extend the compliance dates for the Nutrition Facts Label and Serving Size Final Rules (82 FR 45753), we analyzed regulatory alternatives and considered two options for the time period of the extension of the compliance dates and presented the estimates for what the cost savings to industry would be. We concluded that extending the compliance date by approximately 1.5 years for both categories of manufacturers is a means to balance the importance of ensuring that industry has sufficient time to comply with complex new requirements against the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

With regard to the comment about breath mints and product reformulation, this comment is outside the scope of this rulemaking. The Serving Size Final Rule changed the label serving size for breath mints to ''1 unit.'' The amendments to the Nutrition Facts label regulations became effective on July 26, 2016. This rulemaking, as explained in the preamble to the proposed rule of October 2, 2017, pertains solely to the compliance dates for the Nutrition Facts Label and Serving Size Final Rules (82 FR 45753 at 45754).

B. Comments Outside of Scope of the Proposed Rule

Some comments raised issues that were outside the scope of the proposed rule. In brief, we received comments asking about:

- Changing the label;
- Requiring schools to have education programs relating to the label;
- Requesting FDA to reopen the comment period on the Nutrition Facts Label and Serving Size Final Rules asserting a 3-year stay is needed to obtain additional empirical research data for substantiation of changes to the label made in the final rules; and
- Extending the compliance date for the front-of-package calorie labeling of items sold in vending machines to align with the proposed extension of the Nutrition Facts Label Final Rule.

The final rule pertains solely to the compliance dates for the Nutrition Facts Label and Serving Size Final Rules. Therefore, the comments are outside the scope of this rulemaking.

IV. Effective/Compliance Date(s)

A. Effective Date

The final rule is effective on July 3, 2018.

B. Compliance Date

The compliance date for manufacturers with $10 million or more in annual food sales is January 1, 2020. The compliance date for manufacturers with less than $10 million in annual food sales is January 1, 2021.

V. Economic Analysis of Impacts

We have examined the impacts of the 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 significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is an economically significant regulatory action as defined by Executive Order 12866.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an Agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the Agency publicly proposes for notice and comment or otherwise issues a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This final rule is an Executive Order 13771 deregulatory action. We estimate that this rule generates approximately $61 million in annualized cost savings, discounted relative to year 2016 and using a 7 percent discount rate, over a perpetual time horizon. Details on the estimated cost savings of this final rule can be found in the rule's economic analysis.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We have analyzed this final rule under the Regulatory Flexibility Act and certify that, because this final rule only extends the compliance dates for the Nutrition Facts Label and Serving Size Final Rules, this final rule would 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 final rule would not result in an expenditure in any year that meets or exceeds this amount.

The principal benefit of this final rule to extend the compliance dates is the reduction in the costs to industry of meeting the compliance dates of the Nutrition Facts Label Final Rule and the Serving Size Final Rule. This reduction in costs can be attributed to a reduction in the relabeling and reformulation costs of the Nutrition Facts Label and Serving Size Final Rules. We estimate that, at the mean, the present value of the benefits (*i.e.,* cost savings) of this final rule to extend the compliance dates over the next 20 years is $1 billion using either a 3 percent or 7 percent discount rate (2016$). This is illustrated in table 2. Extending the compliance dates by approximately 1.5 years would reduce the estimated benefits of the Nutrition Facts Label and Serving Size Final Rules because it would delay the realization by consumers of the full annual welfare gains of the Nutrition Facts Label and Serving Size Final Rules. More specifically, an extension of the compliance dates would delay the incorporation of the provisions of the Nutrition Facts Label and Serving Size Final Rules by food manufacturers into their products. We estimate that, at the mean, the present value of the foregone benefits of this final rule to extend the compliance dates over the next 20 years is $0.9 billion using either a 3 percent or 7 percent discount rate (2016$). This is also presented in table 2. We estimate that, at the mean, the present value of the net benefits (that is, cost savings minus foregone benefits) of this final rule to extend the compliance dates over the next 20 years is $0.1 billion using either a 3 percent or 7 percent discount rate (2016$). This is shown in table 2.

TABLE 2—SUMMARY OF THE COST SAVINGS TO INDUSTRY AND FOREGONE BENEFITS TO CONSUMERS OF THIS FINAL RULE TO EXTEND THE COMPLIANCE DATES

[In billions of 2016$]

	Discount rate	Cost savings	Foregone benefits	Net benefits (cost savings—foregone benefits)
Present Value	3%	$1.0	$0.9	$0.1
	7	1.0	0.9	0.1
Annualized Amount	3	0.07	0.06	0.01
	7	0.09	0.08	0.01

Notes: Cost savings to industry, foregone benefits to consumers, and net benefits reflect mean estimates. This final rule extends the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

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

VI. 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.

VII. Paperwork Reduction Act of 1995

This 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.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority

conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: ''. . . no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) . . . .'' The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101–535, 104 Stat. 2353, 2364 (1990)). The final rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act.

IX. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA. Final Regulatory Impact Analysis, Regulatory Flexibility Analysis for Final Rule on ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels and 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; Extension of Compliance Dates.'' April 2018. Available from *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*
2. Sheahan, M. ''FDA Blog Post.'' *Label Insight.* April 5, 2018. Available at *https://blog.labelinsight.com/growing-new-label-adoption-provides-transparency-for-consumers.*
3. Food and Drug Administration, ''Reference Amounts Customarily Consumed: List of Products for Each Product Category; Guidance for Industry; Availability.'' 83 FR 9000 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535368.htm.*
4. Food and Drug Administration, ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Guidance for Industry; Availability. '' 83 FR 8997 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm528532.htm.*
5. Food and Drug Administration, ''The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Draft Guidance for Industry; Availability.'' 83 FR 8953 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm595578.htm.*

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09476 Filed 5–3–18; 8:45 am]

BILLING CODE 4164–01–P2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2017–N–6216]

General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify the needle destruction device, renaming the device to ''sharps needle destruction device,'' a postamendments class III device (regulated under product code MTV), into class II (special controls), subject to premarket notification. FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on new information. The Agency is classifying the device into class II (special controls) to provide a reasonable assurance of safety and effectiveness of the device. This order reclassifies these types of devices from class III to class II and will reduce regulatory burdens on industry because these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: This order is effective June 4, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher K. Dugard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2561, Silver Spring, MD 20993, 240–402–6031, *christopher.dugard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3). Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell*