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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2011–F–0171]

RIN 0910–AH83

Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing this final rule to revise the type size labeling requirements when front-of-pack (FOP) labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. We are taking this action to reduce the regulatory burden on industry, increase flexibility for the labeling of certain articles of food sold from glass-front vending machines, and ensure that consumers continue to have visible FOP calorie information for articles of food at the point of purchase.

DATES: *Effective Date:* This rule is effective November 27, 2019. *Compliance Date:* The compliance date for type size FOP labeling requirements (21 CFR 101.8(b)(2)) for articles of food sold from glass-front vending machines is July 1, 2021.

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.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

We are amending our vending machine labeling regulations in part 101 (21 CFR part 101) by revising the type size requirement in § 101.8(b)(2) (21 CFR 101.8(b)(2)) when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. Our regulations previously required that the FOP calorie declaration type size for articles of food sold from glass-front vending machines be at least 50 percent of the size of the largest printed matter on the label. The final rule requires, instead, that the FOP calorie declaration type size be at least 150 percent (one and one-half times) the minimum required size of the net quantity of contents (*i.e.,* net weight) declaration on the package of the vended food. This change will reduce regulatory burdens on, and increase flexibility for, industry, while ensuring that calorie information is visible to consumers to help them make informed dietary decisions.

B. Summary of the Major Provision of the Final Rule

The final rule revises the type size requirement for calories labeled on the front of the package of vended foods in § 101.8(b)(2) by amending the type size to 150 percent (one and one-half times) the minimum required type size of the net quantity of contents declaration.

C. Legal Authority

This action is consistent with our authority in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)(5)(H)). Section 403(q)(5)(H) requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. In addition, we are issuing this rule consistent with our authority in sections 201(n) (21 U.S.C. 321(n)) and 403(a)(1) and (f) of the FD&C Act. Further, we are issuing this rule under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. We discuss our legal authority in greater detail in section III, ''Legal Authority.''

D. Costs and Benefits

Because this final rule only requires minor revisions to FOP calorie labeling type size requirements when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines, we estimate there are no costs to vending machine operators and potential cost savings to vending machine operators and packaged food manufacturers. We expect the cost savings of this revision to outweigh the costs, with no significant effect on consumer behavior or health.

II. Background

A. Need for the Regulation/History of This Rulemaking

Section 403(q)(5)(H) of the FD&C Act requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. Under section 403(q)(5)(H)(viii) of the FD&C Act, a vending machine operator must provide a sign in close proximity to each article

of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article if: (1) An article of food is sold from the vending machine that does not permit a prospective purchaser to examine the Nutrition Facts label before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase and (2) the machine is operated by a person who is engaged in the business of owning or operating 20 or more vending machines.

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule to implement these labeling requirements (''2014 final rule''). The 2014 final rule, which became effective on December 1, 2016, requires vending machine operators that own or operate 20 or more vending machines (or that voluntarily register with us to be subject to the 2014 final rule) to provide calorie declarations for certain foods sold from vending machines. If FOP calorie labeling is used to meet that requirement, the 2014 final rule requires the calorie labeling be clear and conspicuous and easily read on the article of food while in the vending machine, in a type size at least 50 percent of the size of the largest printed matter on the label (79 FR 71259 at 71291).

After the 2014 final rule's publication, some trade associations and food manufacturers stated that the FOP type size requirement presented significant technical challenges to the packaged food industry and asked us to: (1) Amend the requirement and (2) provide additional flexibility for providing FOP calorie information.

In the **Federal Register** of July 12, 2018 (83 FR 32221), we issued a proposed rule to revise the type size labeling requirements for FOP calorie declarations for packaged food sold from glass-front vending machines such that the minimum type size would be 150 percent (one and one-half times) the size of the net quantity of contents declaration, instead of being based on the largest printed matter on the label. We also asked for comment on two alternate approaches: Requiring the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration (Alternate Approach A) and not specifying any size for the visible nutrition information (Alternate Approach B). We proposed a compliance date of January 1, 2020, and announced our intent to exercise enforcement discretion pending completion of the rulemaking for products sold in glass-front vending machines that: (1) Provided FOP calorie disclosures and (2) complied with all aspects of the 2014 final rule except the type size requirement. Finally, we announced our intent to exercise enforcement discretion, at least until January 1, 2020, for calorie disclosures for gums, mints, and roll candy products sold in glass-front machines in packages that are too small to bear FOP labeling.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 90-day comment period. We received more than 120 comments. The comments came from individual consumers, academia, healthcare professionals, consumer advocacy groups, industry, public health groups, and trade associations. Among other things, the comments discussed:

- *FOP labeling type size.* Some comments said that larger FOP calorie labeling type size would help consumers read the information and make an informed dietary decision, while other comments noted that larger type size would reduce industry flexibility and may have no effect on consumer decisions.
- *Regulatory burdens to industry.* Some comments said we should reduce regulatory burdens and provide additional flexibility for industry while still giving consumers the information they need to make informed dietary decisions; other comments wanted a larger minimum type size for FOP calorie disclosures regardless of any burden to industry.
- *Compliance dates.* Some comments wanted an extended compliance date to allow companies to bring their FOP labeling into compliance with the rule.
- *Whether FDA should:* (1) Maintain the 2014 final rule's type size requirement, (2) finalize the proposed requirement, (3) finalize Alternate Approach A, or (4) finalize Alternate Approach B. Some comments wanted to retain the 2014 final rule's type size requirements and stated that the requirements were the most beneficial to public health. The comments supporting either our proposed type size requirement or an alternate approach generally did not support Alternate Approach B. Many supported the proposed type size, while some said Alternate Approach A would reduce the regulatory burden on industry while still giving consumers the information they need to make informed dietary decisions.

We discuss the comments and our responses to the comments in more detail in part IV of this document.

III. Legal Authority

We are revising the labeling requirements for providing calorie declarations for food sold from certain vending machines, as set forth in this final rule, consistent with our authority in section 403(q)(5)(H) of the FD&C Act. Under section 403(q)(5)(H) of the FD&C Act, certain vending machine operators must provide calorie declarations for certain articles of food sold from vending machines. Under section 403(a)(1) of the FD&C Act, such information must be truthful and non-misleading. Under section 403(f) of the FD&C Act, any word, statement, or other information required by or under the FD&C Act to appear on the label or labeling of an article of food must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Under section 403(a), (f), or (q) of the FD&C Act, food to which these requirements apply is deemed misbranded if these requirements are not met. In addition, under section 201(n) of the FD&C Act, the labeling of food is misleading if it fails to reveal facts that are material in light of representations made in the labeling or with respect to consequences that may result from use. Thus, we are issuing this rule under sections 201(n) and 403(a)(1), (f), and (q)(5)(H) of the FD&C Act, as well as under section 701(a) of the FD&C Act, which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received more than 120 comments on the proposed rule. The comments came from individual consumers, academia, healthcare professionals, consumer advocacy groups, industry, public health groups, and trade associations.

We describe and respond to comments in subsections B through F of this section. We preface each comment discussion with a numbered ''Comment'' and each response by the word ''Response'' to make it easier to identify comments and our responses. We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

B. Description of General Comments and FDA Responses

Many comments generally supported or opposed the proposed rule without focusing on a particular provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Some comments supported the 2014 final rule's requirement that the calorie labeling type size be at least 50 percent of the size of the largest printed matter on the label. The comments expressed concern that the proposed type size of 150 percent of the minimum required net weight declaration may be too small for consumers to see or could be easily missed by hurried consumers or by children. The comments said that the larger type sizes required by the 2014 final rule make it easier for consumers to make informed dietary decisions. One comment suggested that there is no evidence that a reduction in calorie type size will benefit consumers. Another comment said that reducing the type size could lead to less consumer use of FOP calorie declarations and said we should conduct consumer studies to determine the appropriate type size.

(Response 1) The preamble to the proposed rule explained that several industry representatives indicated that the 50 percent type size requirement for FOP calorie labeling presented significant technical challenges to the packaged foods industry (83 FR 32221 at 32223). These challenges included calorie declarations that would be very large on some products and difficulties in label redesign (id.). Additionally, several voluntary FOP labeling programs presented calorie information in sizes ranging from 100 to 150 percent of the minimum size of the net quantity of contents statement, and these FOP labeling programs would be disrupted significantly if the label had to comply with the 50 percent type size requirement in addition to having the voluntary FOP information. For these reasons, we proposed to amend the 50 percent type size requirement. The comments suggesting that we keep the 50 percent type size requirement did not address the technical challenges described in the preamble to the proposed rule or the potential impact to voluntary FOP nutrition labeling programs. Consequently, the final rule revises § 101.8(b)(2) to require the type size of the calorie declaration for articles for food sold from certain vending machines be at least 150 percent of the minimum required size of the net quantity of contents declaration on the package.

Regarding the comments stating that changing the type size requirement would result in declarations that are too small or less useful to consumers, we note that the final rule requires the visible nutrition information to be in a type size ''at least 150 percent'' of the size of the net quantity of contents declaration. This means that the information may be *larger* than 150 percent, and so the rule gives manufacturers the flexibility to make the most efficient and effective use of their label space in presenting the required nutrition information. We also note that both section 403(q)(5)(H)(viii) of the FD&C Act and the final rule require the information to be ''clear and conspicuous.'' Thus, given that a type size of at least 150 percent of the size of the net quantity of contents declaration ensures that the FOP calorie declaration is clear and conspicuous and visible to consumers at the point of purchase, and given that the rule does not limit how large the nutrition information must be, we disagree that the rule will result in declarations that are too small or not useful to consumers.

(Comment 2) Some comments expressed concern that vending operators could assume that simply stocking glass-front machines with products that have FOP declarations complies with vending machine labeling requirements (§ 101.8) and may not provide calorie information in cases where the coil or positioning of a product prevents a consumer from being able to read the FOP calorie declarations before purchasing a product.

(Response 2) We affirm that vending machine operators stocking glass-front machines with products that have FOP declarations in order to satisfy vending machine labeling requirements in § 101.8 must comply with all requirements set forth in § 101.8(b)(2). This means not only complying with minimum type size requirements set forth in this final rule, but also requirements that the prospective purchaser can view the total number of calories for the article of food as sold at the point of purchase. Our regulations, at § 101.8(b)(2), require that FOP calorie declarations be clear and conspicuous and able to be easily read on the article of food in the vending machine, among other requirements. Additionally, our regulations, at § 101.8(b)(1), effectively require that the calories, serving size, and servings per container listed in the Nutrition Facts label be visible to prospective purchasers ''without any obstruction.'' Both § 101.8(b)(1) and (2) are clear that calorie declarations on the food label must be visible, without obstruction, such that we do not find it necessary to further amend or add requirements in § 101.8(b) specifying how a product is to be placed in a vending machine when FOP labeling is used to meet vending machine labeling requirements.

C. Comments on Our Proposed 150 Percent Type Size Requirement and FDA Responses

We proposed to require that FOP calorie information be clear and conspicuous and able to be easily read on the article of food while in the vending machine, in a type size at least 150 percent of the size of the net quantity of contents declaration on the front of the package, and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information (proposed § 101.8(b)(2)) (83 FR 32221 at 32226 through 32227).

We also proposed two editorial corrections to § 101.8(b)(2): Substituting the word ''prospective'' in place of ''perspective,'' and revising the first sentence of § 101.8(b)(2) by inserting a comma after the word ''minimum.''

(Comment 3) Many comments supported a proposed type size of at least 150 percent (one and one-half times) the minimum required size of the net quantity of contents declaration. The comments noted that the 150 percent type size requirement gives industry flexibility, reduces regulatory burdens, provides visible calorie information to consumers so that they can make informed dietary choices, is easy to enforce, allows for the continuation of voluntary FOP labeling initiatives, and standardizes FOP calorie type size.

(Response 3) As we noted in the preamble to the proposed rule (83 FR 32221 at 32223) and in our response to comment 1, the 50 percent type size requirement presented significant technical challenges to the packaged foods industry and also had the potential to significantly disrupt voluntary FOP labeling programs. We agree that revising our regulations to require the type size of FOP calorie declarations to be at least 150 percent the minimum required size of the net quantity of contents declaration will provide flexibility to industry and reduce regulatory burden while continuing to provide visible calorie information to consumers. We reiterate that the rule, by using the terms ''at least 150 percent,'' creates a minimum size requirement and that manufacturers can make the calorie disclosures on FOP labeling even larger if they choose.

(Comment 4) Some comments asked that we clarify our proposed

requirement to state that: (1) The type size must be 150 percent of the size *required* for the net quantity of contents declaration and (2) the type size requirement refers to the quantitative value for calories for FOP declarations and not the word ''calories'' itself. For example, one comment recommended the following language: ''The visible nutrition information must be clear and conspicuous and able to be easily read on the article of food while in the vending machine, with the numeric value for calories appearing in a type size at least 150 percent of the size required by section 101.7(i) of this title for the net quantity of contents declaration on the front of the package.''

(Response 4) We agree, in part, and disagree, in part, with the comments.

With respect to the comment suggesting that we clarify the rule to require the type size to be 150 percent of the size required for the net quantity of contents declaration, we have revised the rule to state that type size must be ''at least 150 percent of the size required by § 101.7(i) for the net quantity of contents declaration'' on the front of the package. By adding language to refer explicitly to our net quantity of contents regulation at § 101.7(i) (21 CFR 101.7(i)), we establish a minimum value on which the visible nutrition information is to be based. In other words, the size requirements set forth in § 101.7(i), rather than the size of the net quantity of contents declaration that is actually used on the package (because § 101.7(i) establishes minimum size requirements rather than specific size requirements), become the starting point for the size of the visible nutrition information in § 101.8(b)(2). We decided to retain the words ''at least'' before ''150 percent'' so that firms can make the visible nutrition information larger if they so choose.

Regarding the comment asking us to clarify that the type size requirement refers to the quantitative value for calories for FOP declarations and not the word ''calories'' itself, we interpret ''visible nutrition information,'' which is the subject of § 101.8(b)(2), to mean ''total calories in the article of food'' (79 FR 71259 at 71266 through 71267). Therefore, the numerical value indicating the total calories, rather than the word ''calories,'' is subject to this final rule's type size requirements.

D. Comments on Our Alternate Approaches and FDA Responses

We invited comment on two alternate approaches in the proposed rule's preamble: Requiring the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration (Alternate Approach A), and not specifying any size for the visible nutrition information (Alternate Approach B) (83 FR 32221 at 32224). Several comments addressed these alternate approaches.

(Comment 5) Some comments supported Alternate Approach A (requiring the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration). One comment said that larger calorie labeling places undue importance on calories and could give a competitive advantage to products with fewer calories and smaller or lighter packages. Another comment said that the approach would ensure the calorie information is visible for consumers while creating a consistent size requirement that is not overly burdensome on industry.

(Response 5) The area of the principal display panel (calculated in square inches or square centimeters) determines the minimum type size that is permitted for the net quantity declaration, which § 101.7(i) further explains. As such, both the 150 percent requirement we are finalizing and Alternate Approach A's 100 percent requirement would be based on the size of the principal display panel. We do not agree that a calorie declaration size based on the overall size of the principal display panel gives a competitive advantage to any particular product because the minimum declaration size will be proportionate to the package size (§ 101.7(i)).

Regarding the comment suggesting that a package with a larger calorie declaration could be at a competitive disadvantage relative to products in smaller or lighter packages, we disagree. The calorie disclosure applies to the food as vended; the weight of the package does not affect the caloric value of the food itself. Furthermore, we do not have (and the comment did not provide) evidence indicating that the size of the calorie disclosure itself will influence a consumer's decision to purchase a food.

We decided not to adopt Alternate Approach A because adopting a type size of at least 150 percent of the minimum required size of the net quantity of contents declaration provides a larger minimum calorie declaration type size, versus Alternate Approach A's 100 percent minimum type size, to the purchaser when they are viewing the vended product through the glass front of a vending machine. When a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, visible nutrition information on the front of package must be large enough, and prominent enough, for prospective purchasers to see and use the information (79 FR 71259 at 71269). We believe that the 150 percent type size requirement for FOP calorie disclosures on foods sold from glass-front vending machines will ensure that the declarations are visible, clear, and conspicuous and able to be easily read by a prospective purchaser, satisfying section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act requirements that nutrition information be visible to a prospective purchaser at the point of purchase.

The 150 percent requirement also provides sufficient flexibility and reduces the regulatory burden for industry, particularly because many manufacturers already use this type size for calorie disclosures. We note that industry comments, particularly comments from small- and medium-sized vended food manufacturers, supported the 150 percent requirement, and such support reinforces our decision to adopt the 150 percent requirement instead of Alternate Approach A.

(Comment 6) Some comments disagreed with Alternate Approach A, saying it would limit the visibility of calorie information. The comments stated that calorie disclosures of this size would be difficult for consumers to read even from a short distance, particularly through the glass front of a vending machine. One comment said that Alternate Approach A would make FOP calorie information generally less prominent in vended food items, reducing the overall efficacy of FOP labeling.

(Response 6) We agree that Alternate Approach A would make FOP calorie declarations less prominent on vended food items because of Alternate Approach A's smaller minimum type size requirement, and for the reasons stated in our response to comment 5, we decline to adopt Alternate Approach A. The comments disagreeing with Alternate Approach A also did not provide, and we are not aware of, data or evidence regarding the limited visibility of calorie information, consumers' impaired ability to read calorie disclosures, or comparative efficacy of FOP labeling under Alternate Approach A as compared to the 150 percent minimum type size requirement.

(Comment 7) Many comments disagreed with Alternate Approach B (FOP calorie disclosures without a type size requirement). For example, some

comments advocated a minimum FOP calorie type size requirement that ensures readability by consumers rather than a ''no type size'' requirement in Alternate Approach B. Other comments said that Alternate Approach B would not help the public, with one comment saying that Alternate Approach B would deny consumers the caloric content transparency that is necessary to make informed decisions about their health. Other comments said that a lack of size specifications would introduce inconsistent labeling across brands and products.

Some comments supported Alternate Approach B and stated that it would provide maximum flexibility for industry.

(Response 7) We have decided not to adopt Alternate Approach B. Vending machine operators that choose products that have FOP labeling must ensure that the visible nutrition information is clear and conspicuous, as required by both section 403(q)(5)(H)(viii) of the FD&C Act and our regulations. Alternate Approach B would provide vending machine operators with no clear standard on what type size is sufficient to be visible, clear, and conspicuous to a prospective purchaser, thus making it difficult for an operator to determine whether a vended food manufacturer's FOP labeling satisfies section 403(q)(5)(H)(viii) of the FD&C Act and our regulations. Conversely, a minimum type size, such as the 150 percent standard that we are adopting in the final rule, provides a workable type size that industry can implement that ensures visibility to consumers.

In addition, amending our type size requirements in § 101.8(b)(2) is consistent with voluntary FOP labeling programs that already present calorie information in type sizes of 150 percent of the minimum size of the net quantity of contents statement on the principal display panel.

E. Comments on the Proposed Compliance Date and FDA Responses

We proposed that covered vending machine operators comply with any finalized requirements from this rulemaking by January 1, 2020 (83 FR 32221 at 32224 through 32225).

(Comment 8) Some comments noted that some products have extended shelf lives, and those products may be in distribution or vending machines, without updated labeling, on the final rule's compliance date. Some comments suggested that we should enforce the final requirements only on those products manufactured after the rule's compliance date. Other comments supported extending the final rule's compliance date to align with the compliance dates for the Nutrition Facts labeling final rule. The comments noted that harmonizing the compliance dates provides for more efficient implementation of the final rules, so that companies must revise labels only once to comply with all requirements.

Conversely, other comments did not support any extension of the final rule's compliance date. One comment stated that the final rule's effective date should be no later than January 20, 2020, because FDA has been working on this matter since 2011 and because the rule is required by the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148). Another comment said that we should finalize a standard and adhere to whatever compliance date we set.

(Response 8) We agree that manufacturers that intend to add FOP calorie disclosures that are consistent with this final rule should have time to revise or update their labeling. Therefore, we have determined that a compliance date of July 1, 2021, is appropriate. This will give industry time to make label changes and move any existing products through distribution chains before the compliance date. We believe this date will have limited impact on consumers' health in the interim because: (1) Any FOP labeling used to meet calorie disclosure requirements must still comply with all aspects of the 2014 final rule except the type size requirement and (2) many manufacturers already use the 150 percent type size for calorie disclosures.

(Comment 9) Some comments asked that we either allow alternate calorie labeling for gums, mints, and roll candy products sold in glass-front machines in packages that are too small to bear FOP labeling or exercise enforcement discretion from the vending machine calorie labeling requirements for these products.

(Response 9) In section VI, we announce our intent to exercise enforcement discretion regarding the calorie disclosure requirements for gums, mints, and roll candy products sold in glass-front machines in packages that are too small to bear FOP labeling.

F. Miscellaneous Comments and FDA Responses

Many comments addressed aspects of vending labeling other than FOP calorie disclosure type size. Some of these, such as comments on the 2014 final rule's effective date, impacts, and economic burdens, and calorie units of measure, fall outside the scope of this rule and many were addressed directly in the 2014 final rule. Other comments, such as those pertaining to additional FOP declarations (such as information on specific nutrients or voluntary disclosures of calories per serving) and other activities that FDA might or should pursue in conjunction with the rule, also are outside the scope of the rule, and we will not address them here.

We discuss the other miscellaneous comments in the following paragraphs.

(Comment 10) Some comments discussed alternate methods of providing calorie information that would comply with the 2014 final rule's requirements, such as on a sign posted near the vending machine. They noted, for instance, that the placement of products within vending machines changes frequently, and so the use of signage generally is impracticable. Some comments said that the vending industry is largely looking to packaged food manufacturers to provide FOP calorie labeling to satisfy our vending machine calorie disclosure requirements.

(Response 10) There are options other than FOP calorie labeling that vending machine operators may choose to satisfy section 403(q)(5)(H)(viii) of the FD&C Act and current vending machine labeling requirements in § 101.8, including allowing the prospective purchaser to view the calories, serving size, and servings per container listed in the Nutrition Facts label on the vending machine food without any obstruction or using reproductions of Nutrition Facts labels, as provided in § 101.8(b)(1), or posting signage with calorie declarations, in, on, or adjacent to the machine, as provided in § 101.8(c). To the extent a vending machine operator provides calorie information for a vending machine food in such an alternate way and otherwise meets the requirements of § 101.8, the vending machine operator would be in compliance with our calorie disclosure requirements.

(Comment 11) Some comments questioned who is subject to the 2014 final rule's requirements, and, by extension, this rule's requirements. One comment asked for clarification on the respective responsibilities of food manufacturers and vending machine companies in complying with this rule; other comments implied that this final rule imposes requirements on manufacturers of food sold from vending machines. Another comment encouraged us to apply our vending labeling requirements to all vending machine operators, regardless of the number of machines they operate.

(Response 11) We stated in the 2014 final rule that section 403(q)(5)(H)(viii) of the FD&C Act and the 2014 final rule

do not apply to suppliers of vending machine food; instead, section 403(q)(5)(H)(viii) of the FD&C Act and the 2014 final rule establish requirements for certain vending machine operators (79 FR 71259 at 71284). The type size requirement in this final rule therefore also establishes requirements for certain vending machine operators and does not apply to suppliers of vending machine food. We recognize that a manufacturer of covered vending machine food may provide calorie information via FOP labeling on their product label and such calorie information may constitute visible nutrition information in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, provided that the applicable requirements of § 101.8(b) are satisfied. However, section 403(q)(5)(H)(viii) of the FD&C Act, the 2014 final rule, and this final rule do not require manufacturers to provide such information. As such, the 2014 final rule and this final rule do not impose requirements on suppliers of vending machine food.

Section 403(q)(5)(H)(viii)(I)(bb) of the FD&C Act states that an article of food requires a calorie declaration if it is from a vending machine that, among other things, is operated by a person who is engaged in the business of owning or operating 20 or more vending machines. Accordingly, our vending calorie disclosure regulations only apply to food sold from vending machines operated by a person: (1) Engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act or (2) not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act.

(Comment 12) One comment expressed concern that allowing voluntary display of calories per serving, along with the required display of calories per package, on vended foods could allow vending machine operators and food manufacturers to bypass the requirement that total caloric contents of the package be clearly labeled in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The comment recommended that we amend § 101.8(c)(2)(i)(C) to include the following sentence: ''If voluntarily disclosed, the calories per serving label shall appear on the food packaging separately and distinctly from the calories per package label such that a prospective purchaser may readily and easily discern between the two.''

(Response 12) As explained in the preamble to the 2014 final rule, our requirements regarding calorie declarations for covered vending machine food mandate declaration of the total calories (79 FR 71259 at 71276). It does not allow vending machine operators to bypass the requirement that total caloric contents of the package be clearly labeled in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

However, as noted in the preamble to the 2014 final rule, we would not object to food manufacturers or vending machine operators voluntarily providing information in addition to total calories to consumers at the point of purchase, provided that such information is truthful and not misleading and otherwise complies with the FD&C Act and FDA regulations (79 FR 71259 at 71267).

V. Description of the Final Rule

The final rule amends our vending machine labeling regulations in part 101 by revising the type size requirement in § 101.8(b)(2) when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. The final rule requires that the FOP calorie declaration type size be at least 150 percent (one and one-half times) the minimum required size of the net quantity of contents (*i.e.,* net weight) declaration on the package of the vended food.

VI. Effective and Compliance Dates

This final rule is effective November 27, 2019. The compliance date for type size FOP labeling requirements (§ 101.8(b)(2)) for articles of food sold from glass-front vending machines is July 1, 2021. We are finalizing this compliance date to provide sufficient time for the packaged food industry to revise their labels, as appropriate, consistent with the new requirements.

In the preamble to the proposed rule, we announced our intent to exercise enforcement discretion, at least until January 1, 2020, with respect to gums, mints, and roll candy products sold in glass-front machines in packages that are too small to bear FOP labeling (83 FR 32221 at 32225). Although the calorie disclosure requirements in § 101.8(c)(2) cover these products, we advise manufacturers of these products and operators of vending machines containing these products of our intent to exercise enforcement discretion beyond January 1, 2020, with respect to compliance with the 2014 final rule's calorie disclosure requirements. We are continuing our enforcement discretion policy for these products because we recognize the challenges of adding compliant calorie information on packages that are too small to bear FOP labeling. As we previously stated, we acknowledge that these products tend to be sold in small packages that do not lend themselves to FOP labeling and are often located or placed in a small space in glass-front machines that may make it difficult to add calorie disclosure signage. For example, we are aware that some glass-front vending machines have trays that are different sizes; the tray width for bags of potato chips is larger than the tray width for a roll of mints or hard candies or for a small package of gum that can make it difficult to add calorie information (81 FR 50303 at 50305). Because we are continuing our enforcement discretion policy for these products, this means that we do not currently intend to pursue actions against vending machine operators that sell gums, mints, and roll candy products that do not meet the calorie disclosure requirements of the 2014 final rule.

VII. 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 rule is not a significant regulatory action as defined by Executive Order 12866. This rule is an Executive Order 13771 deregulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. The 2014 final rule does not impose burdens on the suppliers of vending machine foods. While suppliers are not obliged to engage in FOP calorie labeling, this rule

will allow for greater flexibility for the use of FOP calorie labeling in glass-front vending machines than our previous requirements, potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. Thus, we certify that the 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 $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

In response to requests from the vending and the packaged foods industries to reduce regulatory burden and increase flexibility, we are revising the existing type size requirements when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. The final regulatory impact analysis qualitatively discusses the economic impacts of this final rule, including potential costs, cost savings, and benefits.

Because this final rule only requires minor revisions to FOP calorie labeling type size when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines, we estimate there are no costs to vending machine operators and potential cost savings to vending machine operators and packaged food manufacturers. We expect the cost savings of this revision to outweigh the costs, with no significant effect on consumer behavior or health. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. 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.*

VIII. 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.

IX. Paperwork Reduction Act of 1995

This final rule contains no new collection of information beyond what was described in the December 2014 final rule and is now approved under OMB control number 0910–0782. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. 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. Federal law includes an express preemption provision that preempts any nutrition labeling requirement of food that is not identical to the requirement of section 403(q) of the FD&C Act, except that this provision does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment elects to comply voluntarily with the nutrition information requirements under section 403(q)(5)(H)(ix) of the FD&C Act. This final rule creates requirements for nutrition labeling of food under section 403(q) of the FD&C Act that preempts certain non-identical State and local nutrition labeling requirements.

Section 4205 of the ACA (124 Stat. 119, 576), which amended the FD&C Act to require certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines, also included a Rule of Construction providing that nothing in the amendments made by section 4205 of the ACA shall be construed: (1) To preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the FD&C Act and is expressly preempted under subsection (a)(4) of such section; (2) to apply to 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; or (3) except as provided in section 403(q)(5)(H)(ix) of the FD&C Act, to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of the FD&C Act.

We interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold from vending machines that must comply with the Federal requirements of section 403(q)(5)(H) of the FD&C Act, unless the State or local requirements are identical to the Federal requirements. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either: (1) From vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act or (2) from vending machines operated by a person not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act.

Otherwise, for food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, States and localities may impose nutrition labeling requirements. Under our interpretation of section 4205(d)(1) of the ACA, nutrition labeling for food sold from these vending machines is not nutrient content disclosures of the type required under section 403(q)(5)(H)(viii) of the FD&C Act and, therefore, is not preempted. Under this interpretation, States and localities can continue to require nutrition labeling for food sold from vending machines that are exempt from nutrition labeling under section 403(q)(5) of the FD&C Act. This interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act. There would have been no need to include vending machine operators in the provision that allows opting into the Federal requirements if States and localities could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

In addition, the express preemption provisions of 21 U.S.C. 343–1(a)(4) do 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. This is clear from both the literal language of 21 U.S.C. 343–1(a)(4) with respect to the scope of preemption and from the Rule of Construction at section 4205(d)(2) of the ACA.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* 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, ''Food Labeling: Calorie Labeling of Articles of Food Sold from Certain Vending Machines; Front of Package Type Size, Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Final Small Entity Analysis,'' dated June 2018. Also available at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Revise § 101.8(b)(2) to read as follows:

§ 101.8 Vending machines.

* * * * *

(b) * * *

(2) The prospective purchaser can otherwise view visible nutrition information, including, at a minimum, the total number of calories for the article of food as sold at the point of purchase. This visible nutrition information must appear on the food label itself. The visible nutrition information must be clear and conspicuous and able to be easily read on the article of food while in the vending machine, in a type size at least 150 percent of the size required by § 101.7(i) for the net quantity of contents declaration on the front of the package, and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information.

* * * * *

Dated: September 30, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: October 7, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–23276 Filed 10–25–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2019–N–4328]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Self-Fitting Air-Conduction Hearing Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the self-fitting air-conduction hearing aid into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the self-fitting air-conduction hearing aid's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 28, 2019. The classification was applicable on October 5, 2018.

FOR FURTHER INFORMATION CONTACT: Cherish Giusto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2432, Silver Spring, MD 20993–0002, 301–796–9679, *Cherish.Giusto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the self-fitting air-conduction hearing aid as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a