Appendix G to Part 91—Operations in Reduced Vertical Separation Minimum (RVSM) Airspace

Section 1. Definitions

Reduced Vertical Separation Minimum (RVSM) Airspace. Within RVSM airspace, air traffic control (ATC) separates aircraft by a minimum of 1,000 feet vertically between FL 290 and FL 410 inclusive. Air-traffic control notifies operators of RVSM airspace by providing route planning information.

* * * * *

Section 2. Aircraft Approval

(a) Except as specified in Section 9 of this appendix, an operator may be authorized to conduct RVSM operations if the Administrator finds that its aircraft comply with this section.

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Section 3. Operator Authorization

(a) Except as specified in Section 9 of this appendix, authority for an operator to conduct flight in airspace where RVSM is applied is issued in operations specifications, a Letter of Authorization, or management specifications issued under subpart K of this part, as appropriate. To issue an RVSM authorization under this section, the Administrator must find that the operator's aircraft have been approved in accordance with Section 2 of this appendix and the operator complies with this section.

(b) Except as specified in Section 9 of this appendix, an applicant seeking authorization to operate within RVSM airspace must apply in a form and manner prescribed by the Administrator. The application must include the following:

* * * * *

(c) In a manner prescribed by the Administrator, an operator seeking authorization under this section must provide evidence that:

* * * * *

(2) Each pilot has knowledge of RVSM requirements, policies, and procedures sufficient for the conduct of operations in RVSM airspace.

Section 4. RVSM Operations

* * * * *

(b) * * *

(1) The operator is authorized by the Administrator to perform such operations in accordance with Section 3 or Section 9 of this appendix, as applicable.

(2) The aircraft—

(i) Has been approved and complies with Section 2 this appendix; or

(ii) Complies with Section 9 of this appendix.

(3) Each pilot has knowledge of RVSM requirements, policies, and procedures sufficient for the conduct of operations in RVSM airspace.

Section 5. Deviation Authority Approval

The Administrator may authorize an aircraft operator to deviate from the requirements of §§ 91.180 or 91.706 for a specific flight in RVSM airspace if—

* * * * *

(b) At the time of filing the flight plan for that flight, ATC determines that the aircraft may be provided appropriate separation and that the flight will not interfere with, or impose a burden on, RVSM operations.

* * * * *

Section 7. Removal or Amendment of Authority

The Administrator may prohibit or restrict an operator from conducting operations in RVSM airspace, if the Administrator determines that the operator is not complying, or is unable to comply, with this appendix or subpart H of this part. Examples of reasons for amendment, revocation, or restriction include, but are not limited to, an operator's:

* * * * *

Section 8. Airspace Designation

RVSM may be applied in all ICAO Flight Information Regions (FIRs).

Section 9. Aircraft Equipped With Automatic Dependent Surveillance—Broadcast Out

An operator is authorized to conduct flight in airspace in which RVSM is applied provided:

(a) The aircraft is equipped with the following:

(1) Two operational independent altitude measurement systems.

(2) At least one automatic altitude control system that controls the aircraft altitude—

(i) Within a tolerance band of ±65 feet about an acquired altitude when the aircraft is operated in straight and level flight under nonturbulent, nongust conditions; or

(ii) Within a tolerance band of ±130 feet under nonturbulent, nongust conditions for aircraft for which application for type certification occurred on or before April 9, 1997, that are equipped with an automatic altitude control system with flight management/performance system inputs.

(3) An altitude alert system that signals an alert when the altitude displayed to the flightcrew deviates from the selected altitude by more than—

(i) ±300 feet for aircraft for which application for type certification was made on or before April 9, 1997; or

(ii) ±200 feet for aircraft for which application for type certification is made after April 9, 1997.

(4) A TCAS II that meets TSO C–119b (Version 7.0), or a later version, if equipped with TCAS II, unless otherwise authorized by the Administrator.

(5) Unless authorized by ATC or the foreign country where the aircraft is operated, an ADS–B Out system that meets the equipment performance requirements of § 91.227 of this part. The aircraft must have its height-keeping performance monitored in a form and manner acceptable to the Administrator.

(b) The altimetry system error (ASE) of the aircraft does not exceed 200 feet when operating in RVSM airspace.

Issued under authority provided by 49 U.S.C. 106(f), 40103(b), 40113(a), and 44701(a) in Washington, DC, on December 10, 2018.

Daniel K. Elwell,

Acting Administrator.

[FR Doc. 2018–27401 Filed 12–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2012–N–1210]

Food Labeling; Revision of the Nutrition and Supplement Facts Labels; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the regulations pertaining to the Nutrition Facts and Supplement Facts labels. The amendments correct errors that were made in labeling examples, restore incorrect deletions, correct the edition of a reference cited in the rule, and correct cross-references to other regulations. This action is ministerial or editorial in nature.

DATES: This rule is effective December 21, 2018.

FOR FURTHER INFORMATION CONTACT: Mark Kantor, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2082.

SUPPLEMENTARY INFORMATION:

I. Background

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). 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 the term ''Calories;''

• removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;

• requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances. For example, because there are no analytical methods that can distinguish between dietary fiber (soluble and insoluble fiber) and nondigestible carbohydrates that do not meet the definition of dietary fiber; added and naturally occurring sugars or the various forms of vitamin E; or folate and folic acid, the Nutrition Facts Label Final Rule requires manufacturers to make and keep certain written records to verify the declarations of dietary fiber, added sugars, vitamin E, and folate and folic acid in the labeling of the food associated with such records. The Nutrition Facts Label Final Rule requires these records to be kept for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. A similar requirement exists with respect to added sugars in foods subject to nonenzymatic browning and fermentation because there are no analytical methods that can determine the amount of added sugar in specific foods containing added sugars alone or in combination with naturally occurring sugars, where the added sugars are subject to nonenzymatic browning and fermentation. However, for manufacturers of such foods who are unable to reasonably approximate the amount of added sugars in a serving of food to which the records requirements apply, the Nutrition Facts Label Final Rule allows manufacturers to submit a petition to request an alternative means of compliance; and

• establishing a compliance date of 2 years after the Nutrition Facts Label Final Rule's effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the Nutrition Facts Label Final Rule's effective date. (In the **Federal Register** of May 4, 2018 (83 FR 19619), however, we extended the compliance date for manufacturers with $10 million or more in annual food sales from July 26, 2018, to January 1, 2020, and the compliance date for manufacturers with less than $10 million in annual food sales from July 26, 2019, to January 1, 2021.)

The Serving Size Final Rule requires all containers, including containers of products with ''large'' reference amounts customarily consumed (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, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (*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.

II. Description of the Technical Amendments

Since we published the two final rules in the **Federal Register**, we have noted or have been made aware of errors that appeared in the final rules. Most errors are non-substantive; for example, § 101.9(e)(5) and (6) (21 CFR 101.9(e)(5) and (6)) show sample Nutrition Facts labels. The sample labels, however, differed from the other sample labels in the Nutrition Facts Label Final Rule in that the line underneath ''Saturated Fat'' did not extend completely to the left edge of the label. Through this technical amendment, we are revising the sample labels so that the line extends completely to the left edge of the label.

Other errors reflected inconsistencies between the Nutrition Facts Label Final Rule's requirements and sample labels. For example, one sample label omitted information regarding the number of servings per container and serving size; both information elements are required. Through this technical amendment, we are revising the sample label to include the missing information.

Three errors resulted in the removal of preexisting provisions even though the Nutrition Facts Label Final Rule did not intend to remove those provisions. To the contrary, the preamble to the Nutrition Facts Label Final Rule discussed the provisions as still existing. Consequently, the technical amendment restores those provisions.

Other errors pertained to cross-references; in some instances, the Nutrition Facts Label Final Rule and the Serving Size Final Rule mistakenly referred to a different provision. In another instance, the Nutrition Facts Label Final Rule omitted a cross-reference to another provision. The technical amendment corrects the cross-references.

We describe the amendments in more detail below.

A. Section 101.9(b) and a Cross-Reference

Section 101.9(b)(2)(i) provides, in part, the requirements for serving sizes for products in discrete units (*e.g.,* muffins, sliced products, such as sliced bread, or individually packaged products within a multiserving package). The Serving Size Final Rule revised § 101.9(b)(2)(i) by removing paragraph (b)(2)(i)(E) (which had pertained to the serving size declaration of individual units in certain multiserving packages where the product has a reference amount of 100 grams (or milliliters) or larger) and redesignated paragraphs (b)(2)(i)(F) through (I) accordingly (see 81 FR 34000 at 34040). For example, § 101.9(b)(2)(i)(G) was redesignated as § 101.9(b)(2)(i)(F).

However, the Serving Size Final Rule neglected to revise a reference to previous § 101.9(b)(2)(i)(G) that appears in § 101.9(b)(5)(vi) (which pertains to ounces as a common household measure, with an appropriate visual unit of measure, for products that naturally vary in size). Consequently, we are revising § 101.9(b)(5)(vi) to refer to § 101.9(b)(2)(i)(F).

B. Section 101.9(c)(2) and Statements Regarding Saturated Fat, Trans Fat, Polyunsaturated Fat, and Monounsaturated Fat

Section 101.9(c)(2) discusses how a statement of the number of grams of total fat in a serving must be expressed. Before we issued the Nutrition Facts Label Final Rule, § 101.9(c)(2) contained four subordinate paragraphs that discussed how the number of grams of saturated fat, trans fat, polyunsaturated fat, and monounsaturated fat must be expressed; these subordinate paragraphs were numbered as § 101.9(c)(2)(i) through (iv). The Nutrition Facts Label Final Rule did not amend or revise these subordinate paragraphs; to the contrary, in the preamble to the Nutrition Facts Label Final Rule, we either referred to them to describe an existing requirement or expressly stated that we did not intend to change them (see 81 FR 33742 at 33785, 33860).

Nevertheless, after we published the Nutrition Facts Label Final Rule, we learned that § 101.9(c)(2)(i) through (iv) had been removed from the *Code of Federal Regulations*. Because we did not intend such a result, the technical amendment restores § 101.9(c)(2)(i) through (iv).

C. Section 101.9(c)(6)(i), Fiber, and a Cross-Reference

Section 101.9(c)(6)(i) discusses, among other things, specific isolated or synthetic non-digestible carbohydrates that we have determined to have physiological effects that are beneficial to human health and that must be included in the calculation of the amount of dietary fiber. One such carbohydrate is psyllium husk, and the Nutrition Facts Label Final Rule contained a cross-reference to § 101.81(c)(2)(ii)(A)(*6*) (21 CFR 101.81(c)(2)(ii)(A)(*6*)).

The cross-reference was in error. The correct cross-reference is § 101.81(c)(2)(ii)(B)(*1*), and so we have revised § 101.9(c)(6)(i) accordingly.

D. Section 101.9(c)(6)(iii), Added Sugars, and Simplified Format

Section 101.9(c)(6)(iii) discusses how the ''added sugars'' statement must appear. The provision states, among other things, that if a statement of the added sugars content is not required and, as a result, is not declared on the Nutrition Facts label, then the statement ''Not a significant source of added sugars'' must be placed at the bottom of the table of nutrient values.

However, § 101.9(f) discusses when the declaration of nutrition information may be presented in a simplified format. In general, a simplified format may be used when a food product contains insignificant amounts of eight or more of specific nutrients; these nutrients include ''added sugars.'' Therefore, the technical amendment revises § 101.9(c)(6)(iii) by adding ''Except as provided for in paragraph (f) of this section,'' at the start of the sentence describing where the statement, ''Not a significant source of added sugars,'' must be placed.

E. Section 101.9(c)(8)(ii) and Quantitative Weight and § 101.9(c)(8)(iv) and Retinol Activity Equivalents (RAE) and the Order of Nutrients on the Nutrition Facts Label

Section 101.9(c)(8) establishes requirements related to the disclosure of vitamins and minerals on the Nutrition Facts label. The rule, at § 101.9(c)(8)(ii), discusses the declaration of vitamins and minerals as a quantitative amount by weight and percent of the Reference Daily Intake (RDI). In the preamble to the proposed rule to revise the Nutrition Facts and Supplement Facts labels, we described the proposed rule as requiring the declaration of the absolute amounts for all mandatory and voluntary vitamins and minerals, in addition to the requirement for percent DV declaration; we also said that an exception to the proposed requirement would be Nutrition Facts labels for foods in small packages that have a total surface area available to bear labeling of 40 or less square inches (79 FR 11880 at 11952, March 3, 2014). The preamble to the Nutrition Facts Label Final Rule noted the same exception for smaller packages (81 FR 33742 at 33946).

However, the codified text inadvertently omitted the language creating the exception. Consequently, we are restoring the exception to § 101.9(c)(8)(ii) so that the declaration of quantitative weights for these vitamins and minerals are not required for labels described in § 101.9(j)(13).

Additionally, § 101.9(c)(8)(ii) contains a sentence mentioning the statement of the amount per serving of the vitamins and minerals ''as described in this paragraph.'' To clarify the reference of ''this paragraph,'' the technical amendment revises ''this paragraph'' to read as ''this paragraph (c)(8)(ii)''.

Our regulations, at § 101.9(c)(8)(iv), describe, among other things, the units of measure for certain vitamins and minerals. The rule lists the nutrients, their units of measure, and their RDIs in a table; for vitamin A, the unit of measure is in micrograms RAE. Footnote 2 to the table explains that RAE means retinol activity equivalents and that 1 microgram RAE equals 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.

In the preamble to the Nutrition Facts Label Final Rule, in response to a comment regarding the unit of measure for vitamin A, we explained that the conversions for microgram RAE were 1 retinol activity equivalent (mcg RAE) = 1 mcg retinol, 2 mcg supplemental β-carotene, 12 mcg of *dietary* β-carotene, or 24 mcg of other *dietary* provitamin A carotenoids (α-carotene or β-cryptoxanthin) (81 FR 33742 at 33913) (emphasis added). However, we neglected to insert the word ''dietary'' before β-carotene, α-carotene, and β-cryptoxanthin in footnote 2.

The technical amendment inserts ''dietary'' before β-carotene, α-carotene, and β-cryptoxanthin in the footnote and also renumbers the footnote as footnote 3. The renumbering of the footnote is necessary because the technical amendment also revises the order of the nutrients in the table at 21 CFR 101.8(c)(8)(iv); the nutrients were supposed to be placed in order so that nutrients that must be disclosed on the label appear first. However, the Nutrition Facts Label Final Rule inadvertently neglected to reorder the nutrients in the table to reflect the status of vitamin D, calcium, iron, and potassium as nutrients that must be disclosed. As a result of reordering the nutrients in the table, footnote 2 is now footnote 3.

F. Section 101.9(d)(1)(iii) and Type Size

Section 101.9(d)(1)(iii) establishes the type sizes for information on the Nutrition Facts label. Among other things, the regulation requires information required under § 101.9(d)(9) (regarding the footnote to the Nutrition Facts label) to be in a type size no smaller than 6 point.

In the preamble to the Nutrition Facts Label Final Rule, we discussed how other information pertaining to ''Amount per serving'' and ''% Daily Value'' also would be required to be in a type size no smaller than 6 point (see 81 FR 33742 at 33944 (discussing the type size for ''Amount per serving'') and 81 FR 33742 at 33952 (discussing the type size for ''% Daily Value'')). However, the codified text at § 101.9(d)(1)(iii) omitted the paragraph designations for ''Amount per serving'' and ''% Daily Value,'' which are § 101.9(d)(4) and (6), respectively. Consequently, the technical amendment adds paragraphs (d)(4) and (6) to the information that must be in a type size no smaller than 6 point.

G. Section 101.9(e)(5) and (6) and Corrections to Sample Labels

Section 101.9(e)(5) and (6) show sample Nutrition Facts labels. The sample labels illustrate how dual column labels might appear. Some sample labels, however, differed from the other sample labels in the Nutrition Facts Label Final Rule in that the line underneath ''Saturated Fat'' did not extend completely to the left edge of the label.

The technical amendment revises the sample labels so that the line extends completely to the left edge of the label.

In § 101.9(e)(5), the revised sample label also changes the value for potassium from 45 mg to 40 mg because the declaration of potassium is to be expressed to the nearest 10 mg. increment.

Additionally, in § 101.9(e)(6)(i), we have revised the title for one sample label from ''Dual Column Display'' to ''Dual Column Display, Per Serving and Per Container.'' This revised title should help distinguish this sample label from the other sample label in § 101.9(e)(6)(i). As for the other sample label titled ''Dual Columns, Per Serving and Per Unit''), the sample label inadvertently omitted information regarding the

servings per container and serving size. The technical amendment revises the sample label for ''Dual Columns, Per Serving and Per Unit'' to include information on servings per container and serving size.

In § 101.9(e)(6)(ii), the sample label appeared blurred or difficult to read when printed in the **Federal Register**.

The technical amendment substitutes a better quality image for the sample label. There are no changes to the contents of the sample label itself.

H. Section 101.9(j)(13) and Addresses or Phone Numbers for Obtaining Required Nutrition Information and the Exception for Certain Individual Serving Size Packages

Section 101.9(j)(13)(i) discusses requirements for foods in small packages. The Nutrition Facts Label Final Rule revised § 101.9(j)(13)(i) so that the Nutrition Facts label on small packages would not be required to bear a footnote explaining what the ''% Daily Value'' means and manufacturers could voluntarily include an abbreviated footnote of ''% DV = % Daily Value'' in a type size no smaller than 6 point.

In revising § 101.9(j)(13)(i), we did not intend to affect the preexisting paragraphs at § 101.9(j)(13)(i)(A), which pertains to the use of an address or telephone number where consumers can obtain required information, and § 101.9(j)(13)(i)(B), which pertains to an exception for certain individual serving size packages of food. After we issued the Nutrition Facts Label Final Rule, we were informed that both paragraphs (j)(13)(i)(A) and (B) had, nevertheless, been deleted. Because we did not intend such a result, we are restoring paragraphs (j)(13)(i)(A) and (B) to § 101.9(j)(13)(i) and also correcting an error in § 101.9(j)(13)(i)(B) by replacing the reference to ''§ 101.2(c)(5)'' with ''§ 101.2(c)(2).'' The correction is necessary because § 101.2(c)(5) does not exist, and the correct reference is to § 101.2(c)(2).

I. Section 101.36 and Corrections to the Spelling of Phosphorus, the Listing of Potassium, the Size of Calories, and a Cross-Reference

Section 101.36(b)(2)(i)(B) (21 CFR 101.36(b)(2)(i)(B)) names dietary ingredients that are to be declared on the Supplement Facts label. The Nutrition Facts Label Final Rule incorrectly spelled phosphorus as ''phosphorous,'' so the technical amendment uses the correct spelling. Additionally, we have replaced ''Vitamin A'' with ''vitamin A'' for purposes of punctuation.

Section 101.36(b)(2)(ii)(B) discusses how the amounts of vitamins and minerals must be declared on the Supplement Facts label. In brief, the regulation states that the amounts of vitamins and minerals, excluding sodium and potassium, must be the amount of vitamin or mineral included in one serving of the product, using the units of measurement and levels of significance given in § 101.9(c)(8)(iv). The exclusion regarding potassium was based originally on the fact that there was no RDI value for potassium. The technical amendment deletes ''and potassium'' from the exclusion in § 101.36(b)(2)(ii)(B) because § 101.9(c)(8)(iv), among other things, does set forth the RDI, nomenclature, and unit of measure for potassium. Thus, because § 101.9(c)(8)(iv) sets forth an RDI and units of measure for potassium, the exclusion for potassium in § 101.36(b)(2)(ii)(B) is no longer appropriate.

Section 101.36(e) discusses type sizes for certain information on the Supplement Facts label. The rule specifies a minimum type size for footnotes (among other things) and gives an example of a footnote statement. However, the example, ''Percent Daily Values are based on a 2,000 calorie diet,'' was missing a quotation mark. The technical amendment restores the missing quotation mark for the phrase ''Percent Daily Values are based on a 2,000 calorie diet.''

Additionally, § 101.36(e) contains a sentence specifying the font size for ''Calories'' and the heading ''Calories'' and the actual number of calories per serving. This sentence, however, should have been removed from the codified text because, as we stated in our response to comment 483 in the Nutrition Facts Label Final Rule, many dietary supplement products may contribute a negligible amount of calories (81 FR 33742 at 33939). We stated that the Nutrition Facts Label Final Rule does not require information about calories to be displayed in a larger type size or highlighted on any Supplement Facts labels (id.). Therefore, we are removing the sentence regarding the font size and highlighting for ''Calories'' and the actual number of calories from § 101.36(e).

J. Section 101.36 and Sample Labels

Section 101.36(e)(11) shows two samples of Supplement Facts labels. The sample label in paragraph (e)(11)(ii) has an ingredient list that has ''Sucrose'' as the first ingredient.

The correct term, however, is ''sugar'' instead of ''sucrose,'' so the technical amendment replaces ''Sucrose'' with ''Sugar'' in the sample label.

The sample label in paragraph (e)(11)(iv) has an entry of 0 grams of trans fat.

The technical amendment removes the trans fat line from the sample label because certain dietary ingredients or subcomponents, including trans fat, that are not present or are present in amounts that can be declared as zero, must not be declared on the Supplement Facts label (see § 101.36(b)(2)).

The sample label in paragraph (e)(12) contained two errors. The sample label incorrectly placed choline after potassium when, under § 101.36(b)(2)(i)(B), choline should appear after pantothenic acid. Additionally, the sample label incorrectly gave a value for potassium. Under § 101.36(b)(2), vitamins and minerals cannot be declared on the Supplement Facts label that are not present, or that are present in amounts that can be declared as zero in § 101.9(c) (such as amounts corresponding to less than 2 percent of the RDI for the nutrient). In the sample label that appeared in the Nutrition Facts Label Final Rule, the level for potassium was less than 2 percent of the RDI. Consequently, the technical amendment revises the sample label to provide a level of potassium that would cause potassium to be listed on the Supplement Facts label.

K. Appendix B and Examples of Graphic Enhancements Used by FDA

The regulations at part 101 (21 CFR part 101) contain several appendices. One appendix, identified as Appendix B and entitled ''Examples of Graphic Enhancements used by the FDA,'' illustrates various features of the Nutrition Facts label and identifies type sizes, fonts, and other specifications that we use in our illustrations of the Nutrition Facts label.

When we issued the Nutrition Facts Label Final Rule, we did not update Appendix B to correspond to the Nutrition Facts Label Final Rule's new and revised requirements. The technical amendment, therefore, updates Appendix B so that the illustration corresponds to the Nutrition Facts Label Final Rule. The updated image also changes the value for potassium from 235 mg to 240 mg; the change to 240 mg is consistent with the rounding increments used for potassium when a serving contains greater than 140 mg of potassium. In such cases, the declared value is rounded to the nearest 10 mg increment.

III. The Administrative Procedure Act

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Under 5 U.S.C. 553(b)(3)(B) of the APA, an Agency may, for good cause, find (and incorporate the finding and a brief statement of reasons in the rules issued) that notice and public comment procedure on a rule is impracticable, unnecessary, or contrary to the public interest. We have determined that notice and public comment are unnecessary because these amendments only make technical or non-substantive changes, such as correcting sample labels, correcting cross-references, and restoring provisions that were never intended to be removed. For these reasons, we have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment is unnecessary.

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as provided by an Agency for good cause found and published with the rule (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, we find good cause for this correction to become effective on the date of publication of this action.

IV. Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 101 have been approved under OMB control number 0910–0381.

V. Analysis of Environmental Impact

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

VI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, 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. In § 101.9:

■ a. Revise paragraph (b)(5)(vi);

■ b. Add paragraphs (c)(2)(i) through (iv);

■ c. Revise paragraphs (c)(6)(i) introductory text, (c)(6)(iii), (c)(8)(ii) introductory text, (c)(8)(iv), (d)(1)(iii), (e)(5), and (e)(6)(i) and (ii); and

■ d. Add paragraphs (j)(13)(i)(A) and (B).

The revisions and additions read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) * * *

(5) * * *

(vi) Ounces with an appropriate visual unit of measure, as described in paragraph (b)(5)(iii) of this section, may be used for products that naturally vary in size as provided for in paragraph (b)(2)(i)(F) of this section.

* * * * *

(c) * * *

(2) * * *

(i) ''Saturated fat,'' or ''Saturated'': A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if ''calories from saturated fat'' is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement ''Not a significant source of saturated fat'' shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (½) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) ''Trans fat'' or ''Trans'': A statement of the number of grams of trans fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.,* nonconjugated) double bonds in a trans configuration, except that label declaration of trans fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content. The word ''trans'' may be italicized to indicate its Latin origin. Trans fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the trans fat content is not required and, as a result, not declared, the statement ''Not a significant source of trans fat'' shall be placed at the bottom of the table of nutrient values.

(iii) ''Polyunsaturated fat'' or ''Poly-unsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a serving defined as cis,cis-methylene-interrupted

polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a food other than one that meets the criteria in § 101.62(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iv) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a serving defined as cis-monounsaturated fatty acids may be declared voluntarily except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a food other than one that meets the criteria in § 101.62(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

* * * * *

(6) * * *

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement ''Not a significant source of dietary fiber'' shall be placed at the bottom of the table of nutrient values in the same type size. The following isolated or synthetic nondigestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in § 101.81(c)(2)(ii)(A)), psyllium husk (as described in § 101.81(c)(2)(ii)(B)(*1*)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added nondigestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

* * * * *

(iii) ''Added Sugars'': A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the added sugars content is not required and, as a result, not declared, the statement ''Not a significant source of added sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type, except that fruit or vegetable juice concentrated from 100 percent juices sold to consumers, fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2) of this chapter, fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160 of this chapter, or the fruit component of fruit spreads shall not be labeled as added sugars. Added sugars content shall be indented under Total Sugars and shall be prefaced with the word ''Includes'' followed by the amount (in grams) ''Added Sugars'' (''Includes 'X' g Added Sugars''). It shall be expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of added sugars in the label and labeling of food.

* * * * *

(8) * * *

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age, except quantitative weights for these vitamins and minerals are not required for labels described in paragraph (j)(13) of this section. The declaration of folic acid shall be included as a quantitative amount by weight when added as a nutrient supplement or a claim is made about the nutrient. The declaration of vitamins and minerals in a food, as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement of the amount per serving of the vitamins and minerals as described in this paragraph (c)(8)(ii), calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added as a nutrient supplement, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or the labeling or advertising and the vitamins and minerals are:

* * * * *

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measure	RDI			
		Adults and children ≥ 4 years	Infants [1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin D	Micrograms (mcg) [2]	20	10	15	15
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Vitamin A	Micrograms RAE [3] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Vitamin E	Milligrams (mg) [4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE [5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate [6]	Micrograms DFE [7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8] 71

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.
[2] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.
[3] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms dietary β-carotene, or 24 micrograms dietary α-carotene, or dietary 24 micrograms dietary β-cryptoxanthin.
[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.
[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.
[6] "Folate" and "Folic Acid" must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.
[7] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally occurring folate = 0.6 mcg folic acid.
[8] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

* * * * *

(d)(1) * * *

(iii) Information required in paragraphs (d)(7) and (8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the "Calories" declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11), (e)(6)(ii), and (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and for the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section no smaller than 14 point. The information required in paragraphs (d)(4), (6), and (9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

* * * * *

(e) * * *

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Dual Columns, Two Forms of the Same Food

Nutrition Facts

12 servings per container

Serving size **1/4 cup dry mix (44g)**

	Per 1/4 cup dry mix		Per baked portion	
Calories	**170**		**300**	
		% DV*		% DV*
Total Fat	1.5g	**2%**	16g	**21%**
Saturated Fat	1g	**5%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	0mg	**0%**	60mg	**20%**
Sodium	300mg	**13%**	375mg	**16%**
Total Carb.	36g	**13%**	36g	**13%**
Dietary Fiber	<1g	**2%**	<1g	**2%**
Total Sugars	18g		18g	
Incl. Added Sugars	18g	**36%**	18g	**36%**
Protein	2g		3g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	100mg	8%	100mg	8%
Iron	1mg	6%	1mg	6%
Potassium	40mg	0%	40mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(6) * * *

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

Dual Column Display, Per Serving and Per Container

Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		% DV*
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Dual Columns, Per Serving and Per Unit

Nutrition Facts

12 servings per container
Serving size **1/2 muffin (144g)**

	Per 1/2 muffin		Per 1 muffin	
Calories	**380**		**760**	
		% DV*		% DV*
Total Fat	16g	**21%**	32g	**41%**
Saturated Fat	3g	**15%**	6g	**30%**
Trans Fat	0g		0g	
Cholesterol	50mg	**17%**	100mg	**33%**
Sodium	480mg	**21%**	960mg	**42%**
Total Carb.	56g	**20%**	112g	**41%**
Dietary Fiber	2g	**7%**	4g	**14%**
Total Sugars	32g		64g	
Incl. Added Sugars	30g	**60%**	60g	**120%**
Protein	3g		6g	
Vitamin D	0.1mcg	0%	0.2mcg	2%
Calcium	40mg	4%	80mg	6%
Iron	2mg	10%	4mg	20%
Potassium	190mg	4%	380mg	8%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(ii) The following sample label illustrates the provisions of paragraphs (b)(2)(i)(D) and (b)(12)(i) of this section for labels that use the tabular display.

Tabular Dual Column Display

Nutrition Facts

2 servings per container
Serving size
1 cup (255g)

Calories
220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*		Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**	**Total Carb.**	35g	**13%**	70g	**25%**
Saturated Fat	2g	**10%**	4g	**20%**	Dietary Fiber	6g	**21%**	12g	**43%**
Trans Fat	0g		0g		Total Sugars	7g		14g	
Cholesterol	15mg	**5%**	30mg	**10%**	Incl. Added Sugars	4g	**8%**	8g	**16%**
Sodium	240mg	**10%**	480mg	**21%**	**Protein**	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%	Iron	1mg	6%	2mg	10%
Calcium	200mg	15%	400mg	30%	Potassium	470mg	10%	940mg	20%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

* * * * *

(j) * * *

(13)(i) * * *

(A) The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (*e.g.,* ''For nutrition information, call 1–800–123–4567'').

(B) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in type size no smaller than 6 point or all upper-case type of 1–16 inches minimum height, except that individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, may comply with § 101.2(c)(2).

* * * * *

■ 3. In § 101.36 revise paragraphs (b)(2)(i)(B) introductory text, (b)(2)(ii)(B), (e) introductory text, (e)(11)(ii) and (iv), and (e)(12) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the

left side of the nutritional label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow choline, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate and folic acid, vitamin B12, biotin, pantothenic acid, choline, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and fluoride. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)(*2*) of this section.

* * * * *

(ii) * * *

(B) The amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg). The amount of vitamin D may, but is not required to, be expressed in IUs, in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IUs must appear in parentheses after the declaration of the amount of vitamin D in mcg.

* * * * *

(e) Except as provided for small and intermediate sized packages under paragraph (h)(3)(i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (*e.g.,* ''Amount Per Serving'' and ''% Daily Value'') and for footnotes (*e.g.,* ''Percent Daily Values are based on a 2,000 calorie diet'').

* * * * *

(11) * * *

(ii) Multiple vitamins for children and adults (excludes Servings Per Container which is stated in the net quantity of contents declaration):

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children 1 through 3 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	<1%**	<1%*
Total Sugars	1 g	†	†
Includes 1g Added Sugars		4%**	2%*
Vitamin A (50% as beta-carotene)	450 mcg	150%	50%
Vitamin C	60 mg	400%	67%
Vitamin D	20 mcg	133%	100%
Vitamin E	8 mg	133%	53%
Thiamin	0.9 mg	180%	75%
Riboflavin	0.9 mg	180%	69%
Niacin	11.2 mg	187%	70%
Vitamin B_6	0.9 mg	180%	53%
Folate	300 mcg DFE (180 mcg folic acid)	200%	75%
Vitamin B_{12}	2.0 mcg	222%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
** Percent Daily Values are based on a 1,000 calorie diet.
† Daily Value not established.

Other ingredients: Sugar, sodium ascorbate, gelatin, maltodextrin, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, artificial flavors, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, cholecalciferol, and cyanocobalamin.

* * * * *

(iv) Dietary supplement containing dietary ingredients with and without RDIs and DRVs:

Supplement Facts

Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	% Daily Value
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

* * * * *

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	900 mcg	100%
Vitamin C (as ascorbic acid)	250 mg	278%
Vitamin D (as ergocalciferol)	20 mcg	100%
Vitamin E (as dl-alpha tocopherol)	75 mg	500%
Thiamin (as thiamin mononitrate)	60 mg	5000%
Riboflavin	60 mg	4615%
Niacin (as niacinamide)	60 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	60 mg	3529%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	4167%
Biotin	100 mcg	333%
Pantothenic Acid (as calcium pantothenate)	60 mg	1200%
Choline (as choline chloride)	100 mg	18%
Calcium (from oystershell)	130 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%

Amount Per Packet		% Daily Value
Magnesium (as magnesium oxide)	63 mg	15%
Zinc (as zinc oxide)	11 mg	100%
Selenium (as sodium selenate)	25 mcg	45%
Copper (as cupric oxide)	0.5 mg	56%
Manganese (as manganese sulfate)	5 mg	217%
Chromium (as chromium chloride)	50 mcg	143%
Molybdenum (as sodium molybdate)	50 mcg	111%
Potassium (as potassium chloride)	200 mg	4%
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established.

Other ingredients: Cellulose, stearic acid, and silica.

* * * * *

■ 4. Revise appendix B to part 101 to read as follows:

Appendix B to Part 101—Graphic Enhancements Used by the FDA

Examples of Graphic Enhancements used by the FDA

A. Overall

1. The Nutrition Facts label is boxed and contains all black or one color type printed on a white or neutral background.

B. Typeface and size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats, the typography may be kerned as much as -4 (tighter kerning reduces legibility).

2. Key nutrients and their % Daily Values are set in 8 point Helvetica Black. The "%" symbol also may be set in Helvetica Black.

3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.

4. "Servings per container" is set in 10 point Helvetica Regular and "Serving size" is set in 10 point Helvetica Black and with 1 point of leading. "Amount per serving" is set in 6 point Helvetica Black.

5. "Calories" is set in 16 point Helvetica Black and the numerical value of calories is set in 22 point Helvetica Black.

6. Absolute measures of nutrient content (for example, "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.

7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 8 point bullets.

8. The type for the footnote is set in 6 point Helvetica Regular with 1 point of leading.

C. Rules

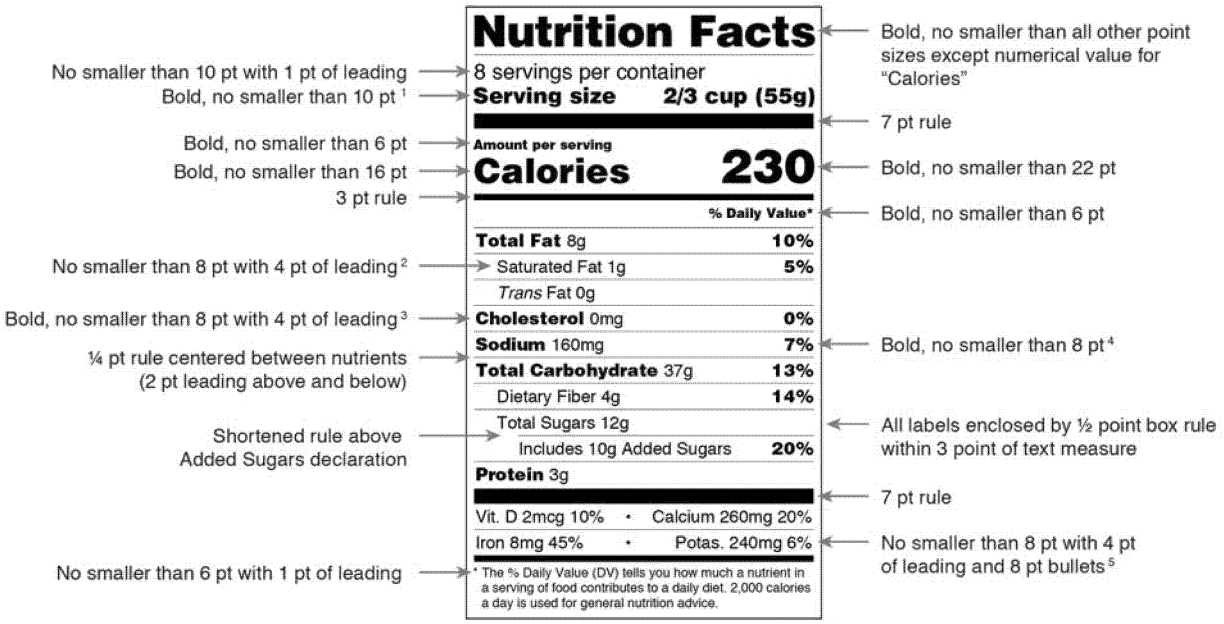
1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie information from the nutrient information.

2. A hairline rule or ¼ point rule separates individual nutrients, as shown in the example. Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules and the bottom half of the label (footnote) has 1 point of leading between the type and the rules. The rule above the "Added Sugars" declaration is shortened as shown in the example.

D. Box

1. All labels are enclosed by ½ point box rule within 3 points of text measure.

Examples of Graphic Enhancements used by the FDA



Dated: December 13, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–27431 Filed 12–19–18; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 543

RIN 3141–AA60

Minimum Internal Control Standards

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC) amends its minimum internal control standards for Class II gaming under the Indian Gaming Regulatory Act to correct an erroneous deletion of the key control standards and to make other minor edits and additions for clarity.

DATES: *Effective Date:* January 22, 2019.

FOR FURTHER INFORMATION CONTACT: Jennifer Lawson at (202) 632–7003 or by fax (202) 632–7066 (these numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (''NIGC'' or ''Commission'') and set out a comprehensive framework for the regulation of gaming on Indian lands. On January 5, 1999, the NIGC published a final rule in the **Federal Register** called *Minimum Internal Control Standards.* 64 FR 590. The rule added a new part to the Commission's regulations establishing Minimum Internal Control Standards (MICS) to reduce the risk of loss because of customer or employee access to cash and cash equivalents within a casino. The rule contains standards and procedures that govern cash handling, documentation, game integrity, auditing, surveillance, and variances, as well as other areas.

The Commission recognized from their inception that the MICS would require periodic review and updates to keep pace with technology and has substantively amended them numerous times, most recently in late 2013 (78 FR 63873).

II. Development of the Rule

On September 21, 2012, the Commission concluded nearly two years of consultation and drafting with the publication of comprehensive amendments, additions, and updates to Part 543, the minimum internal control standards (MICS) for Class II gaming operations (77 FR 58708). The regulations require tribes to establish controls and implement procedures at least as stringent as those described in