Changes to Food and Dietary Supplement Labeling

Presented by Anna Benevente
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About Anna Benevente

Senior Regulatory Specialist

- Anna Benevente holds a Bachelor of Science degree in Biology from The College of William and Mary in Williamsburg, Virginia. Mrs. Benevente has over 8 years of analytical research experience. As a Senior Regulatory Specialist at Registrar Corp, she has been assisting companies with U.S. FDA regulations since 2009. She, along with her team, have researched thousands of products to determine whether they meet the FDA requirements for compliance. In addition, Mrs. Benevente has conducted multiple seminars for trade and customs broker associations. Mrs. Benevente is based at Registrar Corp's headquarters in Hampton, Virginia, where she manages a team of 18 Regulatory Specialists.

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Presentation Overview

- Regulatory History
- Content Changes
- Reference Amounts and Serving Sizes
- Format Changes
- Record Keeping
- Effective and Compliance Dates
- Summary / Questions & Answers

How did we get here?

Regulatory History

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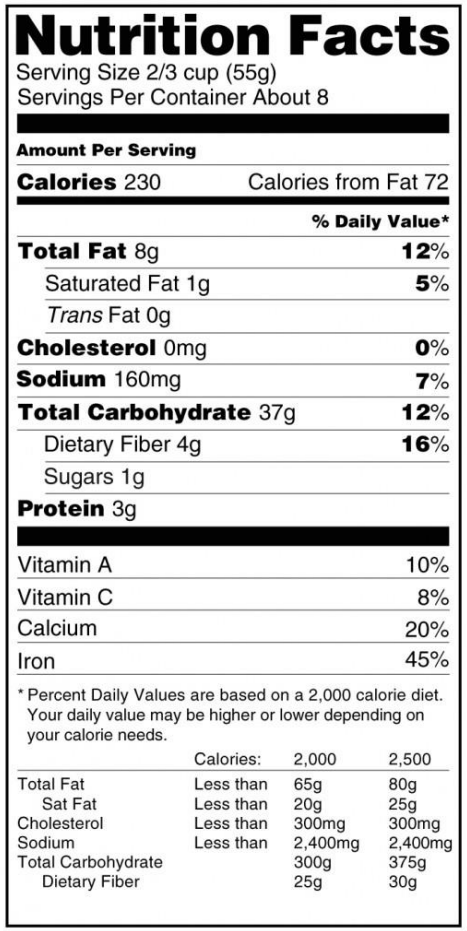
Regulatory History

- Current Nutrition Facts Label has stayed relatively unchanged since passage of the Nutrition Labeling and Education Act (1990)



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

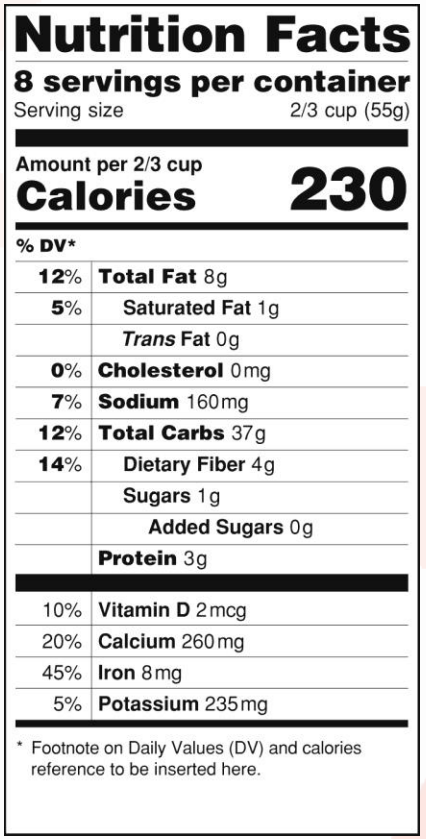
Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12**%
Saturated Fat 1g	**5**%
Trans Fat 0g	
Cholesterol 0mg	**0**%
Sodium 160mg	**7**%
Total Carbohydrate 37g	**12**%
Dietary Fiber 4g	**16**%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Regulatory History

- Based upon new research and nutritional data, FDA issued 2 proposed rules in 2014 to modify the current Nutrition Facts Label in content and format and requested comment
- Supplemental proposed rule issued in 2015 addressed "added sugars"



Nutrition Facts

8 servings per container

Serving size 2/3 cup (55g)

Amount per 2/3 cup	
Calories	**230**
% DV*	
12%	**Total Fat** 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	**Cholesterol** 0mg
7%	**Sodium** 160mg
12%	**Total Carbs** 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	**Vitamin D** 2mcg
20%	**Calcium** 260mg
45%	**Iron** 8mg
5%	**Potassium** 235mg

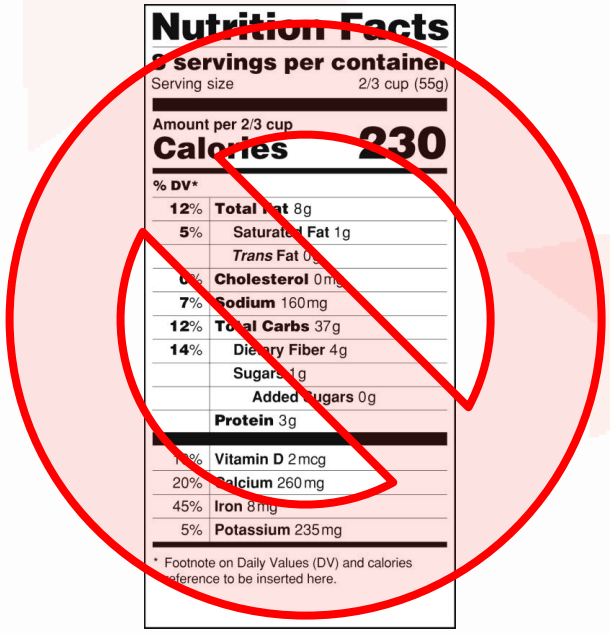
* Footnote on Daily Values (DV) and calories reference to be inserted here.

Regulatory History

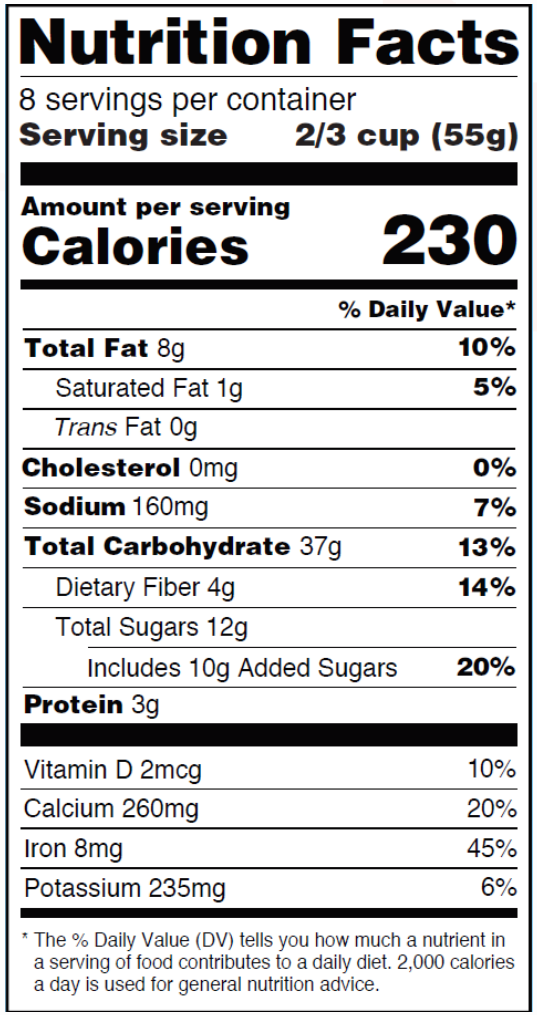
- Final Rules issued May 27, 2016:
  - Food Labeling: Revision of the Nutrition and Supplement Facts Labels
  - Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints

Regulatory History

- Final version of the Nutrition Facts Label is dramatically different than the 1990 and 2014 versions…



Final Version (Standard Format) 2016



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* 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.

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What new information is FDA requiring?

Content Changes

New Content Changes

- Vitamin D and Potassium are now mandatory declarations for the label
- Vitamins A and C are now voluntary
- Calories from fat may no longer be declared
- Fluoride may now be voluntarily declared
- "Sugars" now to be declared as "Total Sugars"

New Content Changes

- Added Sugars must be declared when present at certain amounts
- Quantitative amounts for the four mandatory vitamins/minerals must be given
- Modifications to how folate and folic acid are declared
- New units for Vitamin D, Niacin, Vitamin A, Vitamin E

Dietary Fiber

- FDA has modified the definition for dietary fiber to include only those with demonstrated beneficial physiological effects
  - Nondigestible soluble and insoluble carbohydrates and lignin that are intrinsic and intact in plants, and
  - [beta]-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose
- FDA plans to review data on additional fibers and issue future guidance regarding others that may be included

Added Sugars

- Added Sugars include:
  - Those either added to the food or packaged as such
  - Sugars (free, mono- and disaccharides)
  - Syrups and honey (incl. single ingredient packages)
  - 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

Added Sugars

- FDA provides the following as examples:
  - Brown sugar, sugar
  - Corn syrup and high fructose corn syrup
  - Dextrose
  - Fructose
  - Invert sugar
  - Maltose
  - Trehalose

Added Sugars

- Added Sugars does **not** include:
  - Single strength or 100% fruit juices
  - fruit or vegetable juice concentrated from 100 percent juices sold to consumers (which consumer will reconstitute)
  - 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)
  - fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves
  - fruit component of fruit spreads
  - Sugar alcohols

DRV/RDI Changes

- FDA updated the Daily Reference Value ("DRV") and Reference Daily Intake ("RDI") values for many nutrients, such as:
  - Total Fat 78 g
  - Total Carb 275 g
  - Sodium 2300 mg
  - Potassium 4700 mg
  - Calcium 1300 mg
  - Dietary Fiber 28 g
- FDA established a DRV for Added Sugars at 50 g

DRV/RDI Changes

- Will impact the value of the %DV declared in the label
- Will impact whether a product can make certain nutrient content and health claims
- Updated DRV/RDI values mean products that previously could make claims such as "low sodium" or "high in fiber" may not under the new rules

How have serving sizes changed with the new rules?

Reference Amounts and Serving Sizes

RACC Values

- Serving sizes must reflect the Reference Amount Customarily Consumed (RACC) determined by FDA's review of consumer consumption data
- Reflects what consumers actually eat, not what they should eat
- Multiple RACC values have been changed to reflect new data

Notable RACC changes

- Certain beverage RACCs were increased from 240 mL to 360 mL (such as sodas)
- "All other candies" RACC value decreased from 40 g to 30 g
- Ice cream RACC increased from 1/2 to 2/3 cup
- New RACC category for "appetizers" established
- New RACC category for "after-dinner confectionary"

RACC Example

85 gram chocolate bar

- Previous serving size based upon the 40 g RACC would result in serving size = ½ bar
- NEW serving size based upon 30 g RACC would result in serving size = 1/3 bar

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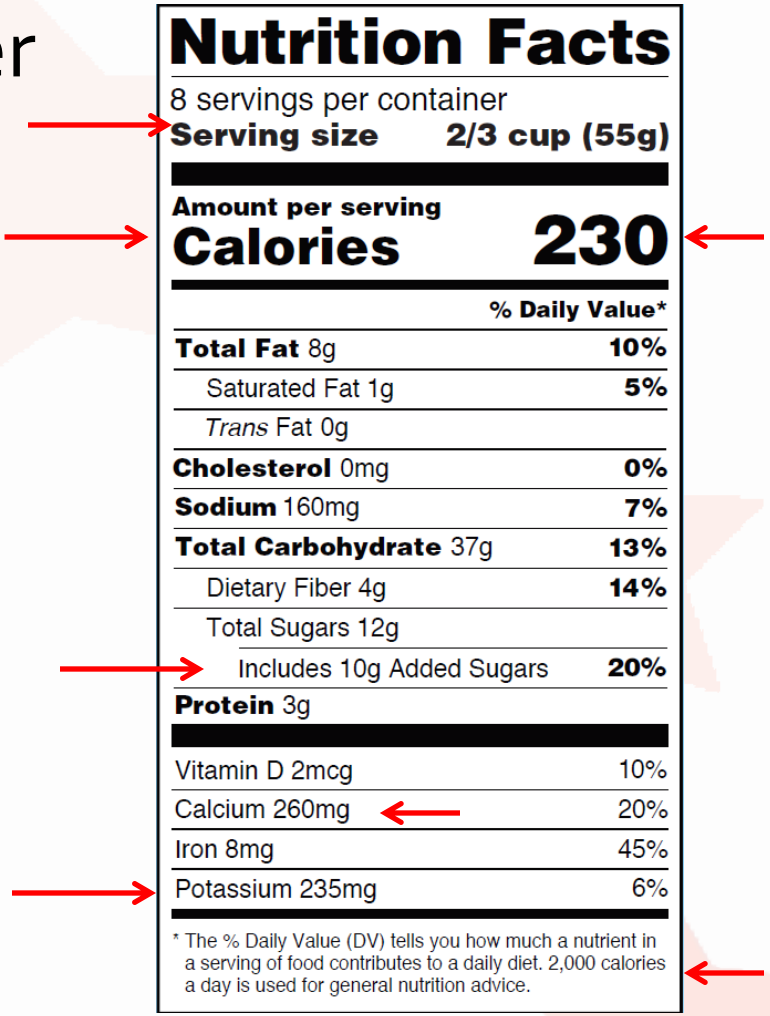
How will the new label look?

Format Changes

Standard Label Changes

- Changes made to the order of nutrients
- Changes made to the footnote
- Changes made to the font sizes of the declarations
- Quantitative amounts of certain vitamins/minerals required



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* 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.

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Simplified Label Changes

- "Simplified" label is permitted when the product meets FDA requirements related to nutritional content

Nutrition Facts

64 servings per container

Serving size **1 tbsp (14g)**

Amount per serving

Calories **130**

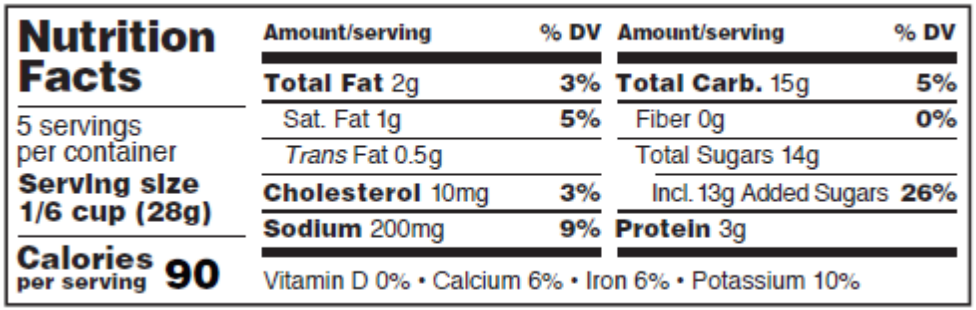
	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

* %DV = %Daily Value

Tabular Label Changes

- "Tabular" label is permitted when product packaging is below a certain size



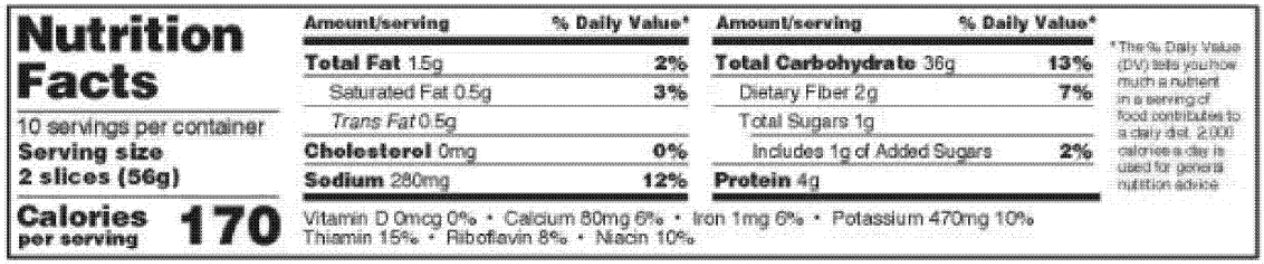
Nutrition Facts

5 servings per container
Serving size 1/6 cup (28g)

Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%



Nutrition Facts

10 servings per container
Serving size 2 slices (56g)

Calories per serving 170

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 36g	**13%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**7%**
Trans Fat 0.5g		Total Sugars 1g	
Cholesterol 0mg	**0%**	Includes 1g of Added Sugars	**2%**
Sodium 280mg	**12%**	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*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.

Linear Label Changes

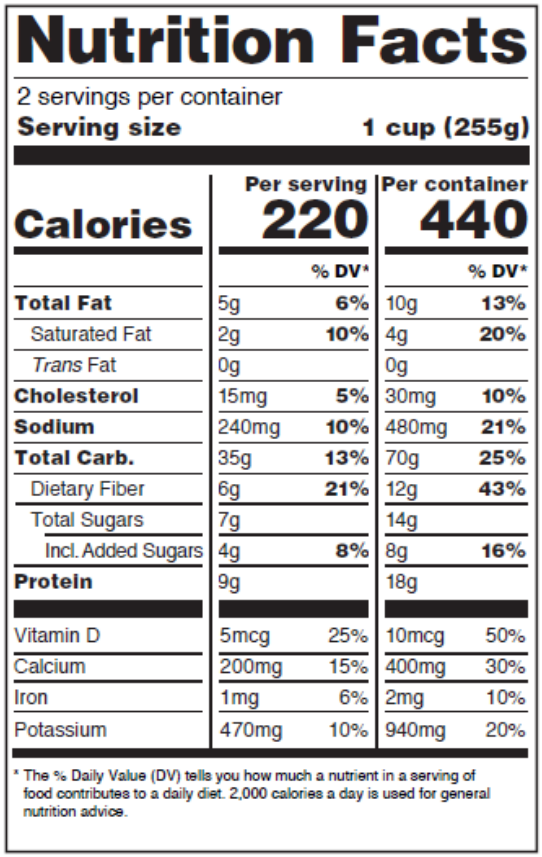
- "Linear" label is only permitted when a tabular chart will not fit on the product packaging


Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5,** **Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (5% DV).

Dual Column Labels

- FDA has mandated "dual column" labels for certain products
- For products in packaging that is 200-300% of the RACC
- For products that are discrete units that are 200-300% of the RACC

Dual Column Label Examples



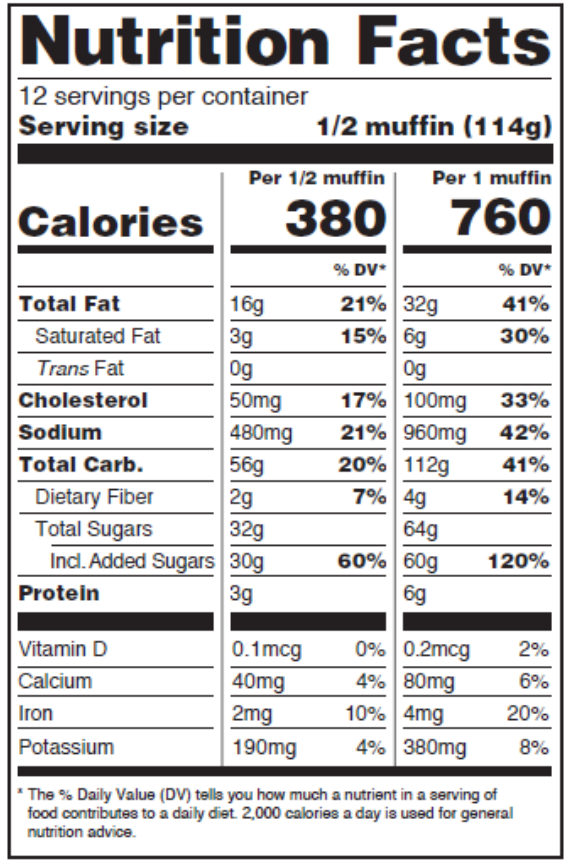
Nutrition Facts

2 servings per container

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

Calories	**Per serving 220**		**Per container 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.



Nutrition Facts

12 servings per container

Serving size **1/2 muffin (114g)**

Calories	**Per 1/2 muffin 380**		**Per 1 muffin 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.

Is there any data that must be kept?

Recordkeeping

Records for Nutrient Declarations

- Generally must be kept for nutrients for which analytical methods are not available
- Records may be analyses of databases, recipes, formulations, batch records

Records for Nutrient Declarations

- Records must show how the nutrient values were determined, when product:
  - Has a mixture of fibers that meet and don't meet the definition of "dietary fiber"
  - Has a mixture of naturally occurring sugars and those that would be considered "added sugars"
  - Is subjected to non-enzymatic browning that results in reduction of "added sugars"
  - Has a mixture of all rac-α-tocopherol and RRR-α-tocopherol (vitamin E)
  - Has a mixture of folic acid and folate

Are dietary supplements affected by the new rule?

Changes to the Dietary Supplement Label

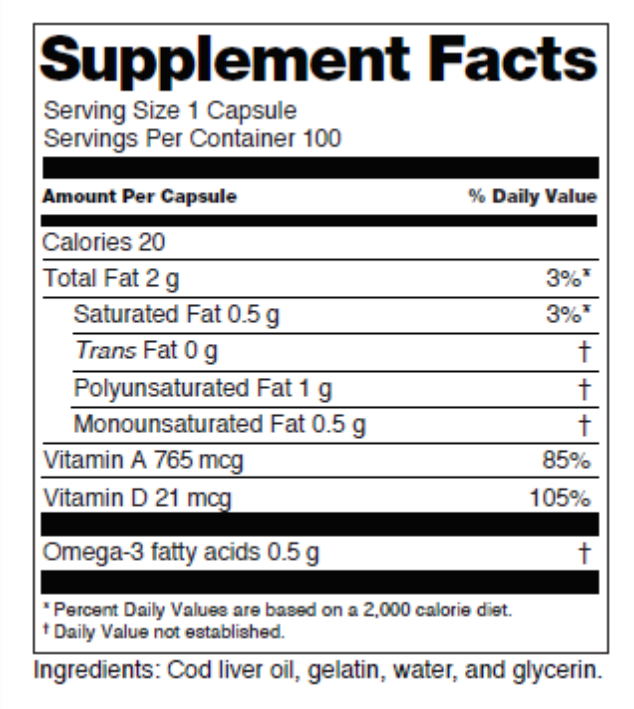
Content Changes

- List of mandatory nutrients no longer includes vitamins A and C
  - Replaced with potassium and vitamin D
  - "Calories from Fat" no longer permitted
- "Added Sugars" and "Total Sugars" must be declared if present
- Changes/additions to regulatory definitions for nutrients in Nutrition Facts Label also apply

Format Changes

- Relatively minor compared to the Nutrition Facts Label
- Size of Calorie declaration will not increase – FDA states that the final rule was in error and will be corrected in a technical amendment
- New disclaimer for supplements intended for children 1-3 years of age:
  - "*Percent Daily Values are based on a 1,000 calorie diet."

Label Examples



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%*
Trans Fat 0 g	†
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.

Supplement Facts

Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

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

Other ingredients: Fructose, lactose, starch, and stearic acid.

How much time do I have to change my labels?

Effective and Compliance Dates

Effective Date

- Effective Date: July 26, 2016
  - New regulations went into effect
  - Replaced the former regulations found in the Code of Federal Regulations

Compliance Dates

- Compliance Dates
  - FDA allows industry time to incorporate the new rules into their packaging
  - Based upon the annual food sales of the manufacturer
  - Sales > $10 Million: July 26, 2018
  - Sales < $10 Million: July 26, 2019

Labeling and Ingredient Review

- Registrar Corp can review food labeling and ingredients for FDA compliance.
- Service includes:
  - A detailed report (typically 40-50 pages) prepared by our team of Regulatory Specialists who scrutinize every element of the food labeling
  - Update to FDA's new labeling format
  - A print-ready graphic file of the revised food label which incorporates our recommended changes.

Questions & Answers