U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

# Regulations for the Labeling of Dietary Fiber in the Nutrition and Supplement Facts Labels

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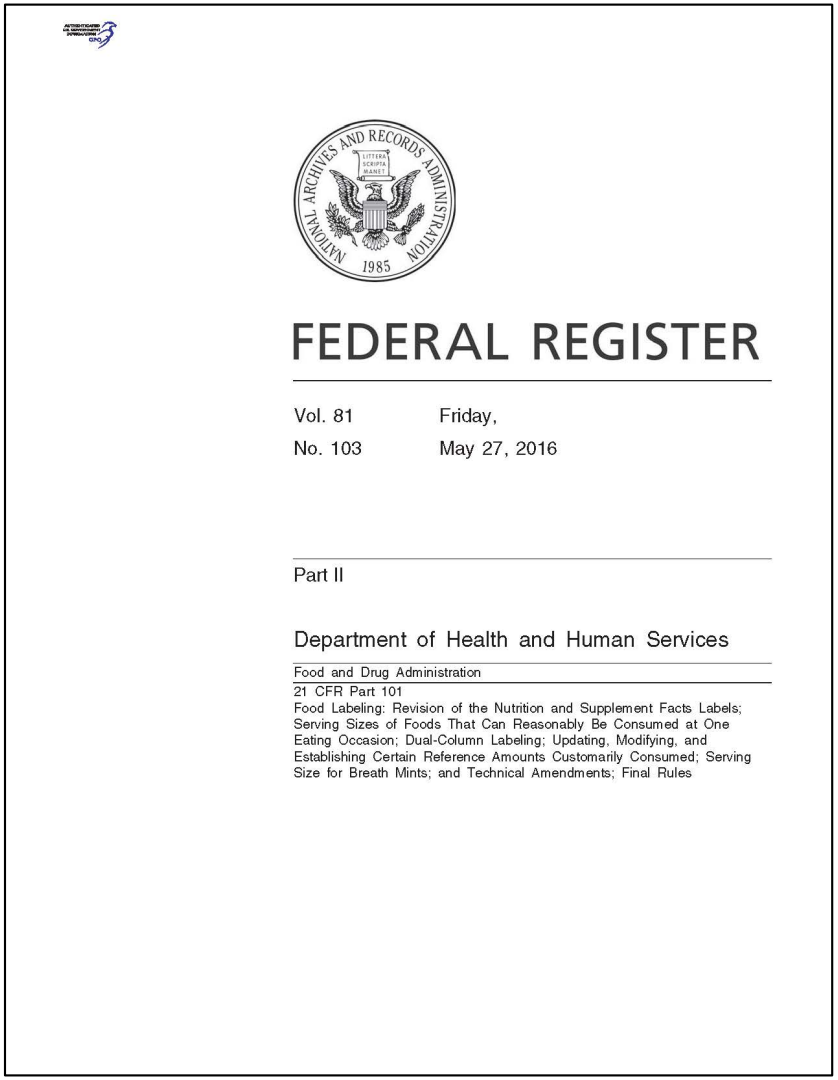
# May 2016 Final Rule



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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; 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; Final Rules

# May 2016 Final Rule

- Amended regulations for Nutrition & Supplement Facts labels

  (21 CFR 101.9 & 101.36)

- Added dietary fiber definition

  (21 CFR 101.9 (c)(6)(i))

# Previous Dietary Fiber Regulation

- Did not define dietary fiber but relied on analytical methods for measuring total, soluble, and insoluble fiber
- Therefore, isolated and synthetic nondigestible carbohydrates could be added to foods and quantified as dietary fiber but without necessarily providing beneficial health effects associated with fiber-containing foods

# Defining Dietary Fiber

IOM established definitions for dietary fiber

- Dietary fiber
  Nondigestible carbohydrates and lignin that are intrinsic and intact in plants
- Added (functional) fiber
  Isolated and synthetic nondigestible carbohydrates that have beneficial physiological effects in humans
- Total fiber (dietary + added/functional fiber)

Includes nondigestible carbohydrates of DP* $\geq$ 3

*DP=Degree of polymerization

(IOM, 2001/2005)

# FDA Dietary Fiber Definition

- Nondigestible soluble and insoluble carbohydrates (with 3 or more monomeric units),* and lignin that are intrinsic and intact in plants, or

- Isolated or synthetic nondigestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health

**May require using newer AOAC methods (such as AOAC 2009.01 and 2011.25)*

# Intact and Intrinsic

- "Intact" - Having no relevant component removed or destroyed
- "Intrinsic" - Originating and included wholly within a food
- Intact and intrinsic fibers are naturally occurring and contain other nutrients that may be associated with beneficial physiological effects

# Beneficial Physiological Effects

Beneficial physiological effects, associated with natural dietary fibers, cannot be assumed to exist when nondigestible carbohydrates are isolated from foods, and especially when synthesized.

# If NOT Intact and Intrinsic

Need to show a physiological benefit such as

- Lowering blood glucose and cholesterol levels
- Lowering blood pressure
- Improving laxation and bowel function
- Increasing mineral absorption
- Reducing energy intake

# To Identify Other Nondigestible Carbohydrates that Meet the Definition

- Submit a health claim petition (21 CFR 101.14)
  - Strong evidence for a relationship with chronic disease risk reduction
  - Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims
- Submit a citizen petition (21 CFR 10.30)
  - Beneficial physiological effect

# Draft Guidance for Industry

"Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition"

- Published: November 23, 2016
- Docket: FDA-2016-D-3401
- Comments due: February 13, 2017

# Draft Guidance

Plant-based foods that contain nondigestible carbohydrates that are intrinsic and intact and that are typically consumed as part of the U.S. diet include fruits, vegetables, whole grains, legumes, and nuts (IOM, 2001).

These fiber-containing foods have been shown to provide health benefits (Dietary Guidelines for Americans, 2015-2020; 21 CFR 101.77)

# Draft Guidance

Nondigestible carbohydrates in fiber-containing foods produced using mechanical processes (e.g., milling), such that the product is still considered a food that contains other nutrients normally found in the foods are also considered intrinsic and intact (IOM, 2002).

Examples include cereal bran, cocoa powder, flours, vegetable purees or pomace, vegetable protein extracts, parts of a food (e.g., outer coat of peas), and nondigestible carbohydrates (e.g., resistant starch) that are created during the normal processing of food (e.g., flaked corn cereal).

# Draft Guidance

- Describes information FDA will rely on:
  - Human Studies
  - Healthy or high risk populations
  - Primary studies (not review articles, etc.)
- Lists questions we plan to consider

# Questions

- Have the studies specified and measured the isolated or synthetic nondigestible carbohydrate?
- Have the studies appropriately specified and measured a physiological endpoint that has a demonstrated beneficial physiological effect?
- Were the study subjects healthy or did they have a disease associated with the physiological effect being studied?

# Questions
## (continued)

- Did the study include an appropriate control group?
- How were the results from the intervention and control groups statistically analyzed?
- Where were the studies conducted?

# Strength of Evidence

- Number of studies and number of subjects per group
- Outcome (beneficial effect, no effect, adverse effect) of the studies. For the outcome of an intervention study to demonstrate a beneficial physiological effect, the intervention group should be statistically significantly different from the control group ($P < 0.05$)

# Strength of Evidence
## (continued)

- Consistency of findings
- Relevance to the general U.S. population
  - Subpopulations
  - Dose

# Rule Identified Dietary Fibers

1. β-Glucan soluble fiber – Health claim on coronary heart disease
2. Psyllium husk – Health claim on coronary heart disease
3. Cellulose – improved bowel function
4. Guar gum – attenuation of blood cholesterol
5. Locust bean gum – attenuation of blood cholesterol
6. Pectin – attenuation of blood cholesterol
7. Hydroxypropylmethylcellulose – attenuation of blood cholesterol

# Notice Requests Scientific Information

Provides science review on 26 fibers and various physiological endpoints

- Published: November 23, 2016
- Docket: FDA-2016-N-3389
- Comments due: February 13, 2017

# Citizen Petitions

As of February 10, FDA has received citizen petitions on

- Isomaltooligosaccharides
- Inulin/oligofructose
- Soy fiber
- Polydextrose
- Resistant starch 4 (phosphorylated)
- Resistant maltodextrin/indigestible dextrin

# Identification of Other Dietary Fibers

- Consider
  - Evidence in science review of 26 fibers
  - Comments to the notice requesting scientific information
  - Information provided in citizen petitions
- Update 21 CFR 101.9 to include additional dietary fibers

# Other Nutrition Regulations Related to Dietary Fiber

# Soluble & Insoluble Fiber Declaration

- No changes
- Continue to use “soluble” & “insoluble”
  - Lack of suitable methods to identify and distinguish between physicochemical effects (e.g., “viscous” and “non-viscous” fiber)
  - FDA must be able to enforce its regulations
- Continue to be voluntary

# DV & Caloric Contribution: Soluble Fiber

- Daily Value for Dietary Fiber
  - 25 → 28 g
- Caloric Contribution
  - Insoluble nondigestible carbohydrate
    0 kcal/g
  - Soluble nondigestible carbohydrate
    4 → 2 kcal/g

# Record Keeping

Record keeping is now required for foods that contain both dietary fiber and added nondigestible carbohydrates that do not meet the definition of dietary fiber

# Compliance Dates for Final Rule

- Small businesses (<$10M revenue) 3 years to come into compliance (7/26/19)
- All other manufacturers will have 2 years to come into compliance (7/26/18)

FDA

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