Nutrition & Supplement Facts
Label Proposed Rule

Crystal R. Rivers, MS
Nutrition Programs
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Proposed Rules Issued

• **Revision of the Nutrition and Supplement Facts Label**
  – Proposes updates to label content *(mandated nutrients, daily values)*
  – Proposes changes to format

• **Serving Sizes, Dual-Column Labeling, Reference Amounts Customarily Consumed, Breath Mints**
  – Proposes revisions for serving size requirements based on updated consumption data
  – Proposes criteria for labeling certain package sizes

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm385663.htm
Key Proposed Changes

- No longer permit “Calories from fat”
- Mandatory listing of vitamins and minerals
- Mandatory listing of added sugars
- Updated Daily Values for vitamins and minerals
- Definition for dietary fiber
- Daily Values for subpopulations
- Record Keeping
Calories

- No longer permit “Calories from fat”
- Retain 2,000 calories as the reference energy intake level for setting Daily Values (DV) that are based on calories (e.g., fat and dietary fiber)
Caloric Value of Nutrients

• Dietary fiber
  – Retain zero kcal/g for insoluble fiber
  – Change the caloric value of soluble fiber from 4 to 2 kcal/g

• Sugar alcohols
  – Isomalt (2.0 kcal/g), lactitol (2.0 kcal/g), xylitol (2.4 kcal/g), maltitol (2.1 kcal/g), sorbitol (2.6 kcal/g), hydrogenated starch hydrolysates (3.0 kcal/g), mannitol (1.6 kcal/g)
General Factors Considered for Labeling of Non-statutory Nutrients

1) Quantitative intake recommendations for establishing DVs (DRIs or Dietary Guidelines for Americans)

AND

2) Public health significance

OR

Other Considerations (e.g. *trans* fat and added sugars)

Statutory nutrients - Total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and total protein
Public Health Significance

• Well-established scientific evidence linking nutrient & chronic disease risk, a health-related condition, or physiological endpoint

• Nutrients for which the RDA* or AI* are based on chronic disease risk, a health-related condition, or physiological endpoint

*RDA = Recommended Dietary Allowance; AI = Adequate Intake
Public Health Significance (cont.)

• Nutrient deficiency with clinical significance
• Inadequate or excess intake of the nutrient and substantial prevalence exists in the general U. S. population of the chronic disease, or health-related or physiological endpoint linked to the particular nutrient
Nutrients of Public Health Significance

• Currently Calcium, Iron, and Vitamins A and C are required on the label
• Based on new analyses to assess nutrient adequacy and other factors
  – Vitamins A and C no longer required
  – Vitamin D and Potassium would be required
  – Calcium and Iron would continue to be required
Nutrients of Public Health Significance (cont.)

- Also proposing that the absolute amounts for all vitamins and minerals be listed on the label, similar to other nutrients (e.g., sodium and total fat)
Quiz Question

What vitamins and minerals are currently required on the Nutrition Facts Label?

A) Calcium, Iron, Vitamin D and Potassium
B) Calcium, Iron, Vitamin A and Vitamin C
C) Iron, Vitamin D, Vitamin C and Potassium
D) Calcium, Vitamin D, Vitamin C and Iron
Added Sugars

• Current label does not provide information on “added sugars.”

• 2010 Dietary Guidelines for Americans (DGAs) recommends reducing the intake of calories from solid fats and added sugars.
  – For most people, no more than 5-15% of total calories from solid fats and added sugars can be reasonably consumed to meet nutrient needs within calorie limits.
  – Americans on average eat 16% of their total calories from added sugars.
Defining Added Sugars

- Any “sugar” added during the processing of foods or consumed separately (sugars, syrups, naturally-occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component [e.g., fruit juice concentrates], other caloric sweeteners)
Justification for Mandating Added Sugars

• Reducing calories from added sugars:
  – Reduces extra calories consumed by Americans
  – Increases intake of nutrient-dense foods without exceeding total calorie needs

• Can assist consumers in maintaining healthy dietary practices consistent with the 2010 DGAs
  – Identify products with added sugars
  – Compare products for amount of “added sugars”
Quiz Answer

What vitamins and minerals are currently required on the Nutrition Facts Label?

A) Calcium, Iron, Vitamin D and Potassium
B) Calcium, Iron, Vitamin A and Vitamin C
C) Iron, Vitamin D, Vitamin C and Potassium
D) Calcium, Vitamin D, Vitamin C and Iron
Daily Values for Vitamins and Minerals

- Propose to continue using the RDA, when available, for setting a DV
- Propose to use the AI for setting a DV
- Propose to continue to use the population-coverage approach for setting the DV
Examples of Changes to the Daily Values

- Dietary fiber – 25 to 28 g
- Sodium – 2,400 to 2,300 mg
- Potassium – 3,500 to 4,700 mg
- Calcium – 1,000 to 1,300 mg
- Vitamin D - 400 IU (10 µg) to 20 µg
- No DV for Added Sugar
Units of Measure

• Propose to no longer use International Units for vitamins A, D and E but rather μg/mg:
  – Vitamin A (μg RAE)
  – Vitamin D (μg)
  – Vitamin E (mg as α-tocopherol)

• Folate – Dietary Folate Equivalents (μg DFE)
Current Dietary Fiber Requirements

• No definition of dietary fiber
• Isolated and synthetic nondigestible carbohydrates without beneficial health effects
  – Can be added to foods and quantified as dietary fiber
• Isolated or synthetic nondigestible carbohydrates with beneficial health effects
  – Can be added to foods but not quantified using the current available analytical methods
Proposed Dietary Fiber Definition

- Non-digestible carbohydrates (≥ 3 monomeric units) and lignin that are intrinsic and intact in plants
- Added (isolated or synthetic) non-digestible carbohydrates (≥ 3 monomeric units) that have been determined by FDA to have a physiological benefit
Declaration of Dietary Fiber

• Health claim petition
  – Barley β-fiber that is added to foods would meet the definition of dietary fiber since it has been authorized for a health claim (21 CFR 101.81)

• Citizen petition
  – We intend to issue guidance to industry on citizen petitions to substantiate physiological effects of added non-digestible carbohydrates that are beneficial to human health
Nutrition Facts Labels for Subpopulations

- Proposed age groups changed from less than 2 years and 2 through 3 years to:
  - 7 through 12 months (older infants)
  - 1 through 3 years (young children)

- DVs established for pregnant/lactating women for the same nutrients as established for the general population using coverage RDA/AI
Labeling of Foods for Older Infants

- Mandatory declaration of percent DV for total fat and total carbohydrate
- The DVs for total fat, total carbohydrate and protein are based on the AI or RDA for older infants.
- The DVs for vitamins and minerals are based on the RDA/AI for infants 7–12 months of age
Labeling of Foods for Young Children

• The DVs are based on the RDAs/AIs for children 1 - 3 years of age for the same nutrients set for the general population

• 1,000 calories is used to set DVs that are based on calories (e.g., fat and dietary fiber)
Record Keeping

- Record keeping would be required for foods that contain:
  - both natural and added sugars
  - both folate and folic acid
  - both dietary fiber and added nondigestible carbohydrates that do not meet the definition of dietary fiber
  - both synthetic and natural vitamin E
Questions?
To begin shortly

The Serving Size Proposed Rule

Cherisa Henderson
Nutrition Programs Staff
Office of Nutrition, Labeling
and Dietary Supplements
FDA:CFSAN