FDA’s Nutrition Innovation Strategy

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HER/NOPREN Healthy Food Retail Working Group Meeting

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Agenda

• Background
• Nutrition Innovation Strategy
• Participating in the regulatory process
• Staying in touch with FDA
• Discussion
FDA Food Responsibilities

• 20¢ of every consumer dollar in the US spent on FDA-regulated products

• FDA regulates safety & labeling of 80% of all food consumed in the United States
  – Ensure that consumers are provided with accurate and useful information in food labeling
  – Encourage food product reformulation to create healthier products

• Close collaboration with CDC, NIH, USDA and other federal partners
Current Eating Patterns in the United States
Percent of the U.S. Population Ages 1 Year and Older Who Are Below, At, or Above Each Dietary Goal or Limit

Note: The center (0) line is the goal or limit. For most, those represented by the orange sections of the bars, shifting toward the center line will improve their eating pattern.

Data Source: What We Eat in America, NHANES 2007-2010 for average intakes by age-sex group. Healthy U.S.-Style Food Patterns, which vary based on age, sex, and activity level, for recommended intakes and limits.

NOTES: Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates using age groups 20–39, 40–59, and 60–74. Overweight is body mass index (BMI) of 25 kg/m² or greater but less than 30 kg/m²; obesity is BMI greater than or equal to 30; and extreme obesity is BMI greater than or equal to 40. Pregnant females were excluded from the analysis.

SOURCES: NCHS, National Health Examination Survey and National Health and Nutrition Examination Surveys.
Number of Deaths and Percentage of Disability-Adjusted Life-Years Related to the 17 Leading Risk Factors in the United States, 2016

Conceptual Framework
FDA & Nutrition

Robust Science → FDA Tools
  → Increase Consumer Understanding
  → Behavior Change
  → Safe and Nutritious Food Supply
  → Public Health Outcome

www.fda.gov
Public Health Outcome

- Reduce risk factors for and the incidence of nutrition-related chronic disease.
- Support HealthyPeople goals to improve nutrition and reduce prevalence of nutrition-related chronic disease.
Nutrition Innovation Strategy
FDA Nutrition Innovation Strategy

“Improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health....The public health gains of such efforts would almost certainly dwarf any single medical innovation or intervention we could discover.”

Scott Gottlieb, M.D.
National Food Policy Conference
March 29, 2018
FDA’s Nutrition Innovation Strategy

Goal: Reduce the burden of chronic disease through improved nutrition
  • Empower consumers with information
  • Facilitate industry innovation toward healthier foods that consumers are seeking

Key Elements
  • Modernizing claims
  • Modernizing standards of identity
  • Modernizing ingredient labels
  • Reducing sodium
  • Implementing menu labeling and the updated Nutrition Facts label, including Nutrition Facts label consumer education campaign

https://www.fda.gov/food/labelingnutrition/ucm602651.htm
Modernizing Claims

• Claims on food and beverage products act as quick signals for consumers about the nutritional benefits of those products, and they can encourage the industry to reformulate products to improve their healthy qualities.

• The nutrient content claim “healthy” is one claim that is ready for a change to be more consistent with current science.

• Along with updating the definition of the claim “healthy” we are exploring ways to depict “healthy” on the package so consumers can easily find it.

• FDA is also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations.
  • Examples include whole grains, low-fat dairy, fruits and vegetables, and healthy oils.
Modernizing Standards of Identity

• Standards of identity establish requirements related to the content and production of certain food products.

• FDA will take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science.

• The goal is to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods.
Modernizing Ingredient Information

• FDA plans to re-evaluate the ingredient information on food packages to see what changes could make it more consumer-friendly
  • E.g., Making information more readable and understandable by changing font or declaring ingredients by names in common usage

• Combining food claims and making ingredient information on labels easier to decipher can allow consumers to choose healthy diets, while staying within caloric guidelines
Voluntary Sodium Reduction: Why are Targets Needed?

- Most sodium comes from salt added to processed and restaurant foods
- It is difficult to meet recommended sodium intake with current food supply
- Overall sodium content of the food supply remains high, despite industry efforts
- Variability in sodium across similar foods in the food supply shows that reductions are possible

Harnack et al., Circulation 2017
Overview of FDA Approach

• Draft, voluntary guidance on sodium reduction targets
  • Gradual approach
  • Targets for 150 categories of food
  • Applies to food manufacturers, restaurants and food service operations

• Draft targets serve as a basis for continued dialogue
Voluntary Sodium Reduction Targets

• Public comment periods closed on October 17, 2016 (2-year targets) and Dec 2, 2016 (10-year targets)
  – Many comments related to targets and food categories received

• Current activities
  – Reviewing comments; considerations:
    • Feedback regarding certain targets and categories
    • Technical role of sodium in foods
Implementing the Nutrition Facts Label

- May 4, 2018: FDA published a final rule extending compliance date
  - Jan 1, 2020 for manufacturers with annual food sales at or above $10 million. Jan 1, 2021 for all others
- Many manufacturers have already started using the new labels
  - Additional time helpful for manufacturers using isolated or synthetic fibers
  - Additional time also allows time for USDA to issue its rule on disclosure of genetically engineered ingredients
- FDA has announced the launch of a major educational campaign surrounding the new nutrition information consumers will be seeing in the marketplace
- FDA issued guidances on issues such as dietary fiber, and serving size declarations
Implementing the Nutrition Facts Label: Guidance Documents for Industry

- Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals
- Draft: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics
- The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels
- Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible carbohydrates Submitted as a Citizen Petition
- Draft: Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products
- Reference Amounts Customarily Consumed: List of Products for Each Product Category
- Small Entity Compliance Guide for Serving Size Final Rule
- FDA’s Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm513734.htm
Calories and other nutrients must be declared for the entire package rather than per serving because people typically consume the package in one sitting.
Dual Column Labeling

- Required on packages that can be consumed in one or multiple sittings
- Nutrition information presented per serving and per package
- For packages that contain 200% and up to and including 300% of the RACC (Reference Amount Customarily Consumed)
  - A 3oz (90g) bag of chips would be labeled per serving [1oz (30 g)] and per package [90 g]
In May of 2016, the FDA announced the new Nutrition Facts label for packaged foods. The purpose of the new label is to make it easier for consumers to make better informed food and beverage choices.

During a recent keynote address at the National Food Policy Conference in Washington, D.C., Scott Gottlieb, the Drug Administration Commissioner, stated regulations dealing with consumer information — as well as labeling, ingredient and standard of identification initiatives — are at the center of a new nutrition innovation strategy.

Implementing Menu Labeling

- **May 7, 2018**: Menu labeling compliance date; FDA released final guidance that provides flexibility on how covered establishments can provide calorie information in ways that meet various business models.
- The new measures, for the first time, create a national and uniform standard for the disclosure of calorie information on menus at chain restaurants and other retail establishments
Menu Labeling: Supplemental Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2373

http://www.fda.gov/FoodGuidances

You may submit written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [FDA–2011–F–0172] listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

May 2018
Example of declaring calories per slice for a build-your-own pizza using a string format
Example of declaring calories for multiple items on a self-service salad bar or a single sign attached to the sneeze guard.
Example of declaring calories for self-service foods on individual signs using gel clings on the sneeze guard
Vending Machine Labeling

- Final Rule issued December 2014:
  - “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines”
  - Compliance date: December 1 2016

- 2018 Proposed Rule:
  - Vending operators may rely on Front of Pack (FOP) labeling to disclose calories on food items in glass front vending machines
  - FDA proposed to amend the type size requirement for FOP calorie disclosures to be at least 150% of the net weight declaration
  - Enforcement discretion until 1/1/2020
    - Glass front vending machines using FOP labeling
    - Gums, mints & rolled candy

For questions related to Vending Machine Labeling: CalorieLabelingVend@fda.hhs.gov.
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FDA’s Rulemaking Process

*FDA solicits public comment when establishing or modifying how a product is regulated*
FDA’s Rulemaking Process

• FDA requests public comment

• Your participation is needed when FDA:
  – publishes proposed rules (also called regulations, which have the force and effect of law),
  – issues guidance documents (statements of our current thinking on a topic), and
  – conducts public meetings and hearings.
How to Find Federal Register Documents

www.fda.gov or www.regulations.gov
Make a difference. Submit your comments and let your voice be heard.

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

Healthy public meeting

What's Trending

Organic Research, Promotion, and Information Orders: Certified Products
Closing on Apr 19, 2017
Memo opening a comment period for this docket.
Closing on May 15, 2017
Endangered and Threatened Species: Petition for Rulemaking To Establish a Whale Protection Zone for Southern Resident...
Closing on Apr 13, 2017
Federal Motor Vehicle Safety Standards: V2V Communications
Closed on Apr 12, 2017
Tobacco Product Standard for N-Nitrosornornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment...
Closing on Jul 10, 2017

Comments Due Soon
Today (55)
Next 3 Days (86)
Next 7 Days (180)
Next 15 Days (367)
Next 30 Days (704)
Next 90 Days (1,033)

Newly Posted
Today (77)
Last 3 Days (273)
Last 7 Days (491)
Last 15 Days (1,025)
Last 30 Days (2,001)
Last 90 Days (5,482)
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Public Health Outcome

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