

FDA Obesity Working Group

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FDA Obesity Working Group Charge:

- develop a clear, coherent, and effective public health message
- outline a public education program
- enhance the food label
- dialogue with restaurant industry
- facilitate development of more & better therapeutics
- identify research gaps (e.g., consumer behavior)
- enlist the help of stakeholders

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Stakeholder Engagement

- October 23, 2003 - Public Meeting
- November 20, 2003 - Workshop - Exploring the Links Between Food Labels & Weight Management
 - government, academia, and private sector, including National Restaurant Association
- December 15, 2003 - Health Professional Roundtable
- December 16, 2003 - Consumer Roundtable
- Public Docket No. 2003N-0338
 - Received over 100 comments

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FDA's OWG - Conclusions



- Problem of Obesity affects all segments of society.
- FDA's report addresses the issue from the perspective of FDA's mission and relevant authorities.
- Report contains a range of short- and long-term recommendations that, along with other private and public efforts, will make a worthy contribution to confronting our Nation's obesity epidemic and help consumers lead healthier lives through better nutrition.

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FDA Report of the Working Group on Obesity



- Report released on March 12, 2004
- View on FDA Website at:
<http://www.fda.gov/oc/initiatives/obesity/>
- The recommendations in the report are centered on the scientific fact that weight control is primarily a function of caloric balance.

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Recommendations



- Labeling
- Enforcement
- Education
- Restaurants/Industry
- Therapeutic
- Research

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Food Label Recommendations from OWG Report:



- Publish an advance notice of proposed rulemaking (ANPRM) to seek comment on how to give more prominence to calories on the food label (e.g., increasing the font size for calories, including a percent Daily Value column for total calories, and eliminating the listing for calories from fat).
- Publish an ANPRM to seek comment on authorizing health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of a health claim for a "reduced" or "low" calorie food might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers."
- Publish an ANPRM to seek comment on whether to require additional columns on the NFP to list quantitative amounts and percent Daily Value of an entire package on those products/package sizes that can reasonably be consumed at one eating occasion (or declare the whole package as single serving).

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Food Label Recommendations from OWG Report (cont.)



- Publish an ANPRM to seek comment on which, if any, reference amounts customarily consumed of food categories appear to have changed the most over the past decade and require updating.
- Carbohydrates: File petitions the agency has received that ask FDA to define terms such as "low," "reduced," and "free" carbohydrate; and provide guidance for the use of the term "net" in relation to carbohydrate content of food.
- Encourage manufacturers to use dietary guidance statements, an example of which would be, "To manage your weight, balance the calories you eat with your physical activity."
- Encourage manufacturers to take advantage of the flexibility in current regulations on serving sizes to label as a single-serving those food packages where the entire contents of the package can reasonably be consumed as a single serving.
- Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions.

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Enforcement Recommendations from OWG Report:



Accurate information in the NFP is crucial for consumers to monitor their intake of calories and nutrients. In particular, meaningful serving sizes can help consumers understand how many calories they consume.

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Enforcement Recommendations from OWG Report (cont.)



- Consider enforcement activities against those manufacturers that declare inaccurate serving sizes.
- Highlight in the Food Labeling Compliance Program enforcement against inaccurate declarations of serving sizes.
- Continue to work with the Federal Trade Commission to target dietary supplement products with false or misleading weight-loss claims.

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Education Recommendations from OWG Report:



The OWG report recommends that FDA focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy eating choices for consumers and with the basic message that "Calories Count."

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Education Recommendations from OWG Report (cont.)



- Establish relationships with private and public sector groups to give consumers a better understanding of the food label and how to use the label to help them make healthier and wiser food choices.
- Pursue relationships with youth-oriented organizations, such as the Girl Scouts of the USA and the 4-H program, to provide educational programs that emphasize caloric balance and proper diet for weight management.

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Restaurants/Industry
Recommendations from OWG Report:



American consumers now spend approximately 46 percent of their food budget on food consumed outside of the home, and these foods account for a significant portion of total calories consumed, especially from quickservice restaurants.

Restaurants/Industry
Recommendations from OWG Report
(cont):



- Urge the restaurant industry to launch a nationwide, voluntary, and point-of-sale nutrition information campaign for consumers.
- Encourage consumers routinely to request nutrition information when eating out.
- Development of a series of options for providing voluntary, standardized, simple, and understandable nutrition information, including calorie information, at the point-of-sale to consumers in restaurants.
- Exploration of the concept of third-party certification of weight-loss diet plans and related products.

Therapeutic Recommendations
from OWG Report:



FDA recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects.

Therapeutic Recommendations from OWG Report (cont.)



- Convene a meeting of a standing FDA advisory committee to address challenges, as well as gaps in knowledge, about existing drug therapies for obesity.
- Continue discussions with pharmaceutical and medical device sponsors about new obesity medical products.
- Revise the 1996 "Guidance for the Clinical Evaluation of Weight-Control Drugs" draft guidance on developing obesity drugs and re-issue it for comment.

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Research Recommendations from OWG Report:



One of the mandates of the OWG was to identify applied and basic research needs that include the development of healthier foods as well as a better understanding of consumer behavior and motivation.

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Research Recommendations from OWG Report (cont.)



- Support and collaborate, as appropriate, on obesity-related research with others, including NIH.
- Collaborate with the U.S. Department of Agriculture/Agricultural Research Service on a USDA-sponsored national obesity prevention conference in October 2004.
- Pursue five other areas of obesity research: (1) information to facilitate consumers' weight management decisions; (2) the relationship between overweight/obesity and food consumption patterns; (3) incentives for product reformulation; (4) the potential for FDA-regulated products unintentionally to contribute to or result in obesity; and (5) the extension of basic research findings to the regulatory environment.

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Back to Basics



"We're going back to basics, designing a comprehensive effort to attack obesity through an aggressive, science-based, consumer-friendly program with the simple message that 'Calories Count.'"

- FDA Deputy Commissioner Lester M. Crawford, DVM, Ph.D.
