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WHAT BUSINESSES NEED TO KNOW ABOUT FDA'S PLAN TO COMBAT OBESITY

by

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As part of its plan to combat the nation's growing obesity epidemic, the Food & Drug Administration (FDA) recently released a report prepared by the agency's Obesity Working Group (OWG). Among other things, the report includes recommendations for steps that can be taken to improve food labeling and suggests that the agency should urge restaurants to voluntarily provide calorie and nutrient information. In addition, the report supports FDA's plans regarding the development of obesity therapeutics.

The report is significant for industry because it offers insight into the future regulatory steps FDA will likely take to combat obesity. The recommendations set forth in the report provide a good roadmap for industry to follow when considering or making internal changes that will bring existing products more in line with the agency's concerns about obesity and weight management. A brief overview of the OWG's recommendations to FDA is provided below.

1. Proposed Rulemakings. The report recommends that FDA pursue several rulemakings to change existing requirements for food labels, in particular, urging the agency to publish several advance notices of proposed rulemakings to seek comment on the following issues:

- how to better emphasize calories on food labels, e.g., increasing the font size for calories;
- whether to modify the Nutrition Facts Panel (NFP) to list quantitative amounts and Percent Daily Values for entire packages when products can reasonably be consumed during one eating occasion;
- whether to update any existing reference amounts customarily consumed; and
- whether to authorize health claims on foods that meet FDA's definition of "reduced" or "low" calorie.

In addition to pursuing rulemakings on changes to existing food labeling regulations, the report recommends that FDA encourage manufacturers to use dietary guidance statements on their products, e.g., "To manage your weight, balance the calories you eat with your physical activity." The report also suggests that manufacturers should be encouraged to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, e.g., "Instead of cherry pie, try our delicious low-fat cherry yogurt — 29 percent fewer calories and 86 percent less fat." The report further advises FDA to encourage manufacturers to take advantage of the flexibility in current food labeling regulations on serving sizes to label as single servings those food packages the entire contents of which can reasonably be consumed as a single serving. Finally, the report urges FDA to take action on the petitions it has received requesting definitions for terms such as "low," "reduced," and "free" as they pertain to carbohydrates.

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2. Voluntary Nutritional Information at Restaurants. In addition to its recommendations for changes to prepackaged food labels, the report includes recommendations for the restaurant industry. Specifically, the report suggests that FDA should encourage the restaurant industry to voluntarily provide point-of-sale nutritional information to consumers.

3. Obesity Therapeutics. Regarding the development of obesity therapeutics, the OWG report supports FDA's plans to take the following actions:

- convene an advisory committee to address challenges with existing therapies;
- continue discussions with pharmaceutical and medical device sponsors about new obesity medical products; and
- revise and reissue for comment the 1996 draft "Guidance for the Clinical Evaluation of Weight-Control Drugs," which offers recommendations on the design and conduct of clinical studies aimed at demonstrating the effectiveness and safety of weight-loss medications.

4. Increased Enforcement Action. The report also offers several recommendations for FDA to take enforcement action against manufacturers to ensure that information in NFPs, particularly regarding serving sizes, is accurate. In particular, the report recommends that FDA consider enforcement activities against manufacturers that inaccurately declare serving sizes on their products and highlight these actions in the Food Labeling Compliance Program.

What the Changes Mean for Industry. The recommendations presented in the OWG report offer industry an opportunity to assess current business practices in light of the regulatory changes FDA is likely to implement to combat obesity. There are several actions industry should consider taking now to prepare for what could be significant regulatory reforms.

1. Evaluate the Potential for Reformulating Products. As they did when FDA issued its rule to require trans-fat labeling, food processors should consider the potential for reformulating products to make them more healthful, *e.g.*, low-fat or low-calorie versions of existing products. In addition, processors may want to consider the benefits of reformulating products to make them eligible to bear currently approved health and nutrition claims.

2. Reconsider Current Marketing Tactics. Food processors should evaluate changes that can be made to their existing marketing practices to promote the various benefits and health aspects of their products according to consumer interest, and their conformance with FDA regulations. Consumer focus groups can provide valuable feedback to manufacturers about what product information is of particular interest to consumers. In addition, proposed rulemakings in this area offer processors an opportunity to comment to the agency regarding the direction in which they think FDA should move with potential rules to ensure that industry's views are reflected.

3. Anticipate and Prepare for Changes to Nutrition Labeling. Manufacturers should monitor FDA rulemakings in this area very closely and consider commenting on potential changes, either individually or through trade associations. In addition, manufacturers should look for ways to use the flexibility afforded by the existing nutrition labeling regulations to make their products more friendly to weight-conscious consumers. For instance, manufacturers could conduct a review of their products to assess whether current regulations would allow any of those products to be labeled as single servings. Finally, the restaurant industry should begin to explore ways to provide consumers with nutritional information about their menu items.

The OWG report encourages FDA to undertake many regulatory reforms to address obesity in the United States. It is critical that industry not only begin to prepare for these changes, but become actively engaged in the rulemaking process, thus ensuring that any FDA action accurately reflects the views and concerns of industry, as well as the interests of consumers.