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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

**[Docket No. 2004N-0463]**

RIN 0910-AF22

**Food Labeling; Prominence of Calories**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking.

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**SUMMARY:** The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of its nutrition labeling regulations to give more prominence to calories on food labels. FDA is issuing this ANPRM as part of the Obesity Working Group (OWG) recommendations to address the Nation's obesity problem. Comments on how to give greater emphasis to calories on the nutrition label will inform FDA's rulemaking.

**DATES:** Submit written or electronic comments by *[insert date 75 days after date of publication in the Federal Register]*.

**ADDRESSES:** You may submit comments, identified by Docket No. 2004N-0463 and/or RIN number 0910-AF22, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include Docket No. 2004N-0463 and/or RIN number 0910-AF22 in the subject line of your e-mail message.
- Fax: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):  
Division of Dockets Management (HFA-305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1450.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Nutrition Labeling Regulations*

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535) amended section 403(q)(1)(C) (21 U.S.C. 343(q)(1)(C)) of the Federal

Food, Drug, and Cosmetic Act (the act) to require that certain foods under FDA's jurisdiction bear nutrition information that provides for, among other things, the total number of calories derived from any source, and the total number of calories derived from total fat in each serving size or other unit of measure. In accordance with the NLEA, FDA issued regulations establishing requirements for nutrition labeling (58 FR 2079, January 6, 1993) (the nutrition labeling final rule). These regulations require the listing of total calories and calories from fat, with the exception that calories from fat is not required on products that contain less than 0.5 gram of fat in a serving (§ 101.9(c)(1)(ii) (21 CFR 101.9(c)(1)(ii))). When calories from fat is not listed, the statement "Not a significant source of calories from fat" must be placed at the bottom of the nutrition label (§ 101.9(c)(1)(ii)). In addition manufacturers may voluntarily list calories from saturated fat (§ 101.9(c)(1)(iii)).

In the nutrition labeling final rule we established, among other things, regulations on the format and content for the listing of calories in the "Nutrition Facts" panel (58 FR 2079, January 6, 1993). These regulations provided that "Calories" must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and highlighted (§ 101.9(d)(1)(iv)). The nutrition labeling final rule also provided that information on total calories and calories from fat in the "Nutrition Facts" panel must follow the heading "Amount Per Serving" and be declared in one line with enough space to clearly differentiate between "Calories" and "Calories from fat", unless "Calories from saturated fat" is voluntarily declared, in which case they should appear in a column, with total "Calories" at the top, followed by "Calories from fat" and "Calories from saturated fat" (§ 101.9(d)(5)). Exceptions to some of these provisions are provided for foods that contain two or more separately packaged foods that

are intended to be eaten individually (§ 101.9(d)(13)), foods that contain insignificant amounts of seven or more of certain specified nutrients (§ 101.9(f)), foods intended for infants and children less than 2 years of age (§ 101.9(j)(5)), dietary supplements (§ 101.9(j)(6)), and foods in small and intermediate-sized packages (§ 101.9(j)(13)).

### *B. The FDA Report of the OWG*

On March 12, 2004, FDA released its report of the OWG outlining an action plan to confront the Nation's obesity problem (Ref. 1). The recommendations in the report centered on the scientific fact that weight control is primarily a function of caloric balance and therefore focused on a "calories count" emphasis. One of the OWG report's principal recommendations involves food labeling. The OWG report noted that comments FDA received at its public meeting, its workshop, and those submitted to the OWG docket<sup>1</sup> expressed concern with the prominence of caloric information on food labels since weight loss and weight management are dependent on caloric balance. The OWG recommended that, among other actions, FDA should request comments on ways to give more prominence to calories on the food label.

## **II. Agency Request for Information**

Over the last decade, since the mandatory nutrition labeling regulations were implemented, there has been an increasing awareness that obesity is becoming a major public health problem in the United States. The ability to determine the caloric content of packaged foods is critical for consumers,

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<sup>1</sup> During its tenure, the OWG met eight times. The OWG received briefings from several invited experts from other government agencies, held one public meeting, one workshop, two round table discussions (one with health professionals/academicians, and one with consumer groups), and solicited comments on obesity-related issues, directing them to the docket established in July 2003 (Docket No. 2003N-0338).

especially consumers who are trying to control total caloric intake. Therefore, FDA requests comment on the following questions:

- How would consumer awareness of the caloric content of packaged foods be increased by amending nutrition labeling regulations to give more prominence to the declaration of calories per serving?
- What methods should be considered for increasing prominence, e.g., should the font size be increased for the listing of “Calories” from the current requirement of 8-point type, and/or should extra bold type or a different style of type be used?
- How does the listing “Calories from fat” adjacent to “Calories” affect consumers’ focus on the total calories of a food?
- What are the advantages and disadvantages of changing the listing for “Calories from fat” from mandatory to voluntary or eliminating it from the nutrition label? What data is there on how consumers use the listing of “Calories from Fat?”
- How would providing for a percent daily value (%DV) column for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet?
- Should the number of calories per serving or per package be required to be declared or be voluntary on the front or principal display panel in addition to the declaration in the “Nutrition Facts” panel? What would be the basis for the additional requirement and what would be the best manner to declare the information? What consumer research data would be needed to show that the current calorie information in the “Nutrition Facts” panel is not effective?

In addition to the previously stated questions, FDA requests comment on other possible approaches to give more prominence to calories on food labels.

### **III. Future Analysis of Benefits and Costs**

To help us determine which regulatory options might solve the problems associated with consumer misunderstanding of information on calories and for the agency's future analysis of benefits and costs associated with those options, we request comments, including available data, on the following questions:

- How do consumers use calorie information on food labels? Is calorie content used to determine how much of a given food to eat, or to determine which foods, out of a range of similar products, to eat?
- If calorie labeling affects decisions on whether to eat a food and on how much to eat, how would the effects of the following requirements differ: A requirement to display the number of calories per serving on the principal display panel or a requirement to increase the prominence of the calories per serving in the "Nutrition Facts" panel?
- Participants in focus groups have asked for calorie labeling based on amounts that they would be likely to consume. What are reasons for and against calorie counts that reflect the amounts people are likely to consume. What do consumers currently think the calories on packaged foods represent? If an amount of calories is prominently placed on the principal display panel, would consumers assume the amount to be for the entire package or for a single serving?
- How would the display of caloric content per package on principal display panels encourage more competition based on the caloric content of packages? How would it result in repackaging products offered in smaller packages, or change the kinds of products offered?

- How do most consumers use the fact that the %DV is based on a 2,000 calorie diet?
- If manufacturers could make label comparisons of different calorie content of foods in different sized packages, what would be the likely change in the distribution of package sizes available to consumers? What types of calorie labeling are most likely to encourage a broader range of package sizes? (See the ANPRM on Serving Sizes of Products that Can Reasonably be Consumed at One Eating Occasion published in this issue of the **Federal Register**.)
- The information on calories on the food label is scientifically-based, but does not include any recommendations on the amounts one should eat. What are the advantages and disadvantages of adding recommendations to the food label?
- Describe some alternative, simpler ways to help consumers determine the caloric intake based on what they eat? What are the advantages and disadvantages of these options?
- Are you aware of any research, consumer or industry-based, that can assist the agency to answer any of these questions?

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulation create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers and producers respond to the changes in calorie labeling. We will use the information from comments to help determine ways to estimate the possible consumer responses to various changes. The comments

will also contribute to our estimates of the effects of regulatory options on small entities.

#### **IV. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal Government holidays.

1. Report of the Obesity Working Group, "Calories Count," March 12, 2004 (<http://www.cfsan.fda.gov/~dms/owg-toc.html>).

#### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of

this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: \_\_\_\_\_

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