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.

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 the agency's nutrition labeling regulations to give more prominence to calories on food labels. FDA is issuing this ANPRM in response to recommendations of the Obesity Working Group (OWG), which was created by the Commissioner of Food and Drugs (the Commissioner) to develop an action plan to address the Nation's obesity problem. Comments on whether and, if so, how to give greater emphasis to calories on the nutrition label will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by June 20, 2005.

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*. 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 Federal Food, Drug, and Cosmetic Act (the act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. The cornerstone of the NLEA is the requirement that packaged foods bear a Nutrition Facts Panel (NFP), which provides product-specific information on serving size, calories, and nutrient content. FDA's final regulations establishing nutrition labeling were published in 1993 (58 FR 2079, January 6, 1993) (the nutrition labeling final rule).

With respect to calorie information, FDA's nutrition labeling final rule requires the listing of total calories and calories from fat, with the exception that ''Calories from fat'' information is not required on products that contain less than 0.5 gram of fat in a serving (§ 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) (21 CFR 101.9(c)(1)(ii))). In addition, manufacturers may voluntarily list calories from saturated fat (§ 101.9(c)(1)(iii)).

The nutrition labeling final rule specifies the format and content for the listing of calories in the NFP and provides that ''Calories'' must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and be highlighted (§ 101.9(d)(1)(iv)). The nutrition labeling final rule also provides that information on ''Calories'' and ''Calories from fat'' in the NFP 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 ''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 Report of FDA's OWG

In August 2003, the Commissioner created the OWG and charged it to develop an action plan covering the critical dimensions of the obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels; communication and education efforts; the role of industry and restaurants; and therapeutic interventions for obesity. The OWG met eight times and received briefings from several invited experts from other government agencies. In addition, the OWG 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 a docket established in July 2003 (Docket No. 2003N–0338) (referred to in this ANPRM as ''the Obesity docket''). The final report issued by the OWG centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a ''calories count'' emphasis for FDA actions (Ref. 1).

A principal aspect of the Commissioner's charge was for the OWG to ''develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity.'' After considering the legal requirements concerning food labeling and the limited data on consumer familiarity

with, and use of, food label information (described in section I.C of this document), the OWG recommended that FDA: (1) Develop options for revising or adding caloric and other nutritional information on food packaging, (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake, and (3) evaluate this information to make evidence-based decisions on which options to pursue. This ANPRM will focus only on the OWG recommendations pertaining to giving more prominence to calories.

C. Data Concerning the NFP and Calorie Information

The OWG reviewed research conducted by FDA and others, described more fully in ''Calories Count'' (Ref. 1), that shows that most consumers are familiar with the nutrition information on food labels and that they use this information primarily for evaluating the nutrition quality of specific food products. However, the percentage of consumers who use the NFP information productively for weight management purposes is low (Ref. 1). In addition, the OWG also reviewed results of focus group research conducted by FDA in November and December 2003 to provide, among other things, preliminary information on the participants' attitudes and behaviors towards nutrition information on food labels. In this research, among other things, FDA asked participants questions aimed at determining consumer attitudes and behaviors towards changes in the presentation of calorie information in the NFP and calorie information on the front label of food packages.

Participants in FDA focus groups cared about nutrition labeling and reported using the NFP. While many participants said they were interested in calories, many also pointed to multiple concerns that went beyond the labeling of calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium (Ref. 1).

In terms of calorie-related variations in the NFP, the focus groups tested participant understanding of several food label designs, including one similar to the current NFP but with some modifications. These included a relatively larger font size for the calories line, a %DV (daily value) for calories, and removal of the listing for ''Calories from fat.'' Many of the participants in these studies did not comment on the changes in the label until they were pointed out to them (Ref. 1).

Focus group participants were also shown a design that included a ''starburst'' with the amount of calories per serving placed on the front of the label (i.e., the principal display panel (PDP)), as a way to give greater prominence to calories. The respondents felt that this design was misleading, i.e., that the manufacturer was trying to indicate that the entire product (as opposed to a single serving) had fewer calories than it actually had. Other groups were shown a design that included a white square with the amount of calories for the entire package. The responses of those shown this white square design were mixed (Ref. 1).

Findings from focus group research yield only qualitative data and should not be viewed as nationally representative of consumers' views. Quantitative experimental data are necessary to make reliable and verifiable conclusions of consumers' views. However, focus group research can shed some interesting light on the complex issues covered by the OWG and are useful for identifying quantitative research needs.

In addition to the literature review and focus group research described more fully in Ref. 1, we have also reviewed the written and public comments submitted to the Obesity docket. Several of these comments suggested that FDA develop ways to emphasize calories on the food label. In particular, these comments suggested that the label should focus less on fat and more on calories and overall diet, and that calories should be listed on the front, or on the PDP of the package in clear, bold lettering. Other comments noted that research should be conducted to determine whether the current calorie listing is meaningful to consumers. We agree with the comments that more research is needed, and that the highlighted comments are important considerations. However, before recommending changes to the food label, the agency wants to develop a better understanding of how consumers currently use calorie information on the NFP, and then assess whether the NFP requires modification to be effective in facilitating positive dietary change (Ref. 1).

D. Recommendations From the OWG Concerning Calorie Labeling

Based on information presented to and gathered by the OWG, its Report observed that, despite evidence of a positive correlation between label use and certain positive dietary choices (e.g., selection of lower sodium or lower fat content foods), the trend towards obesity has accelerated over the last decade (Ref. 1). The OWG hypothesized that consumers may not take advantage of the available information on the food label to control their weight, may not appreciate how the information could be used for weight management purposes, or may find it to hard to apply the available information to such purposes (Ref. 1). Therefore, the OWG recommended that FDA issue an ANPRM to solicit public comments on how to give more prominence to calories on the food label. Possible changes suggested by the OWG were as follows: (1) Increasing the font size for calories; (2) providing for a %DV for calories; and (3) eliminating the ''Calories from fat'' listing, as this may take the emphasis away from the listing of ''Calories'' (Ref. 1).

II. Agency Request for Information

The ability to determine the caloric content of packaged foods is critical for consumers, especially consumers who are trying to control total caloric intake and manage their weight. While the current NFP does allow consumers to determine the caloric content of packaged foods, it may be, as suggested by the OWG Report, that modifying the food label to give more emphasis to calorie information would benefit consumers in weight control and maintenance. To help the agency determine which regulatory options provide consumers with information that is most useful in weight control and weight management, and for any future analysis of benefits and costs associated with those regulatory options, we request comments and available data on the following questions.

A. Questions Concerning Prominence of Calorie Information on Food Labels

- 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? Why or why not?
- How would a more prominent listing of calorie information change the way consumers use the NFP in deciding what to eat?
- What methods could be considered for increasing prominence? For example, 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?
- Would providing for a %DV disclosure for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet? Why or why not?

B. Questions Concerning ''Calories From Fat''

Section 403(q)(1)(C)(ii) of the act (21 U.S.C. 343) states that total calories from fat must be declared on the food label, unless the Secretary [of Health and Human Services] determines that the listing is not necessary to assist consumers in maintaining healthy dietary practices. When the nutrition labeling final rule was published in 1993, the Dietary Guidelines for Americans (1990) recommended that diets be low in fat (Ref. 2). The current Dietary Guidelines for Americans (2005) recommends that diets be moderate in fat with most fats coming from polyunsaturated and monounsaturated fatty acids (Ref. 3). Moreover, the current Dietary Guidelines for Americans recommends maintaining body weight in a healthy range by balancing those calories consumed from foods and beverages with those calories expended. Based on the information in the previous sentences, we request comments and data on the following questions:

- What data is there on how consumers use the listing of ''Calories from fat?''
- How does the listing ''Calories from fat'' adjacent to ''Calories'' affect consumers' focus on the total calories of a food?
- What are the advantages or disadvantages of eliminating the listing for ''Calories from fat'' from the nutrition label?
- What data would be needed to determine whether the listing of ''Calories from fat'' is or is not necessary to assist consumers in maintaining healthy dietary practices?

C. Questions About Use of Calorie Information on Food Labels

Based on preliminary results from focus group research, discussed in this ANPRM, we request comments and data on the following questions:

- 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? Why or why not?
- 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 PDP or

A requirement to increase the prominence of the calories per serving in the NFP?

- What do consumers currently think the calories on packaged foods represent?

D. Questions About Reformulation of Foods Or Redesign of Packaging

Changing the regulations on calorie labeling may have an effect on what producers offer for sale. FDA has no prior information about whether new requirements for calorie labeling would simply change the way currently existing foods are packaged, or if the new requirements would change the formulation of foods offered for sale. In light of this information:

- Would the display of caloric content per package on PDPs encourage more competition based on the caloric content of packages and, if so, how?
- If the calorie content per serving were required to be more prominently displayed on the NFP, would it encourage more competition based on the calorie content of the food? Would the result be products reformulated to have fewer calories per serving, for example greater use of no calorie sweeteners? Would it result in any repackaging of products offered? How would this option change the kinds of products offered?
- If the calorie content per package were required to be prominently displayed on the PDP, would it encourage more competition based on the calorie content of the food? Would the result be repackaging of products into smaller units, for example repackaging cookies into 100 calorie packages? Would there be any incentive to reformulate under this option? How would this option change the kinds of products offered?
- Are you aware of any research, consumer or industry-based, that can assist the agency to answer any of the previous questions?

III. Future Analysis of Benefits and Costs

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. References

The following references have 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.

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

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Dietary Guidelines for Americans,'' 3d ed., pp. 14–15, 1990.

3. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Dietary Guidelines for Americans 2005,'' pp. vii-viii, 2005.

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: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N–0456]

RIN 0910–AF23

Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

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 the agency's nutrition labeling regulations concerning serving size.