between 9 a.m. and 4 p.m., Monday through Friday.

1. DHHS, Public Health Service (PHS), ''The Surgeon General's Report on Nutrition and Health,'' U.S. Government Printing Office, Washington, DC, pp. 139 to 143, 157 to 161, 165, and 167 to 174, 1988.

2. FNB/NAS, *Diet and Health*, National Academy Press, Washington, DC, pp. 355 to 356, 549 to 553 and 556 to 561, 1989.

3. Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, ''The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure,'' *Archives of Internal Medicine*, 153:154 to 183, 1993.

4. Nutrition Committee, American Heart Association, ''Dietary Guidelines for Healthy American Adults—A Statement for Health Professionals from the Nutrition Committee, American Heart Association,'' *Circulation*, 94:1795 to 1800, 1996.

5. LSRO, ''Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships, 4. Sodium and Hypertension,'' Bethesda, MD, December 1991.

6. FNB, National Research Council, ''Recommended Dietary Allowances,'' 10th ed., National Academy Press, Washington, DC, pp. 247–261, 1989.

7. USDA, DHHS, ''Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans,'' USDA, Washington, DC, 1995.

8. USDA, DHHS, ''Nutrition and Your Health: Dietary Guidelines for Americans,'' 4th ed., Home and Garden Bulletin No. 232, 1995.

Dated: December 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–33921 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0168]

Food Labeling; Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the nutrition labeling regulations to change the label serving size for the product category ''Hard candies, breath mints'' to one unit. This action is in response to a petition to provide a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion. In a related issue, FDA is proposing to allow the declaration of caloric amounts of less than 5 calories in the nutrition label.

DATES: Submit written comments by March 16, 1998. Submit written comments on the information collection provisions by January 29, 1998. See Section V of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5662.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the Nutrition Labeling and Education Act (hereinafter referred to as ''the 1990 amendments''), FDA, among other actions, issued a proposal on serving sizes (56 FR 60394, November 27, 1991). FDA proposed a reference amount customarily consumed per eating occasion (hereinafter referred to as ''reference amount'') of 15 grams (g) for ''Baking candies * * * and hard candies'' but no separate reference amount for breath mints (56 FR 60394 at 60419).

The agency received several comments from hard candy manufacturers opposing the uniform 15-g reference amount for hard candies (58 FR 2229 at 2266, January 6, 1993). The comments stated that the 15-g reference amount would result in the serving size of breath mints being the entire package, and that, therefore, breath mints should have a separate smaller reference amount. Most comments recommended a reference amount of one piece. One comment disagreed, however, arguing that several pieces may be consumed during one eating occasion. None of the comments that requested a reference amount based on pieces included any data to support their request.

One comment submitted data from a home use mail survey that supported 2 g as the customarily consumed amount for large breath mints. FDA carefully examined the data from this survey and noted that it only tested the manufacturer's own brands of candies and breath mints. However, in the final rule for serving sizes, because these data were the only breath mint data available to FDA, the agency created a separate product category for ''Hard candies, breath mints'' with a reference amount of ''2 g'' (58 FR 2229 at 2297). The 2 g reflected the weight of one breath mint (Ref. 1).

II. The Petition and Other Communications

FDA received a petition dated April 20, 1994 (Docket No. 94P–0168), from Ferrero USA, Inc., requesting that the agency amend the product category for ''Sugars and Sweets: Hard candies, breath mints'' to create a separate product category with a 0.5-g reference amount for small breath mints (weighing 0.5 g or less) that fulfill the same breath-freshening function as a larger mint. The manufacturer submitted study data not only on small breath mints but also on five large breath mint products. The manufacturer asserted that the data establish that their small breath mints (0.38 g each) are consumed one mint at a time, and that the majority of consumers never eat 2 g of small breath mints, equivalent to five mints, during an entire day.

The company also stated that consumers chose the small breath mints for their breath freshening ability and lower caloric content. The manufacturer stated that their trademarked slogan has been ''The 1 1/2 calorie breath mint,'' based on a serving size of ''1 mint,'' and that changing this slogan would result in an economic hardship. The petitioner concluded that the serving size for small breath mints should be ''1 mint'' and requested that FDA create a separate product category for small breath mints with a reference amount of 0.5 g.

The agency received correspondence opposed to, and in support of, this petition. The opposing comments (Docket No. 94P–0168, comments 1 and 2) stated: (1) That the facts presented in the petition did not support the 0.5 g (one mint) reference amount because nearly half of the users surveyed consumed two or more mints per occasion; (2) that the attempt to establish such an extremely narrow reference category to accommodate a single product runs counter to one of the principal objectives of the 1990 amendments, to provide consistency in labeled serving sizes among comparable and interchangeable products; (3) that ''breath-freshening function'' is not the

statutory standard for the reference amount category and would inappropriately require FDA to apply subjective criteria to determine the correct product category for small breath mints; (4) that basing the reference amount on breath-freshening function would be a dangerous precedent for the agency because, unlike artificial sugar and salt substitutes, there is no established methodology for determining breath-freshening function; (5) that granting the petition could result in the agency being inundated by requests for new or alternate serving sizes for products purporting to have a functional property; and (6) that the petitioner was making a mockery of FDA's petition process by already using an illegal ''1 mint'' serving size.

In rebuttal (Docket No. 94P–0168, amendment 1 and comment 3), the petitioner argued: (1) That the change recommended in the petition would make it easier for breath mint consumers to compare the nutritional composition of competing breath mint products, regardless of size, on a per mint basis; (2) that comparison on a mint-to-mint basis is in keeping with the intent of the 1990 amendments because it would accurately reflect the customarily consumed amounts of small breath mints that are comparable to large mints in terms of breath freshening; (3) that the functional utility of breath mints is a necessary element of the product category definition because the consumption behavior of consumers is directly related to this functional utility, analogous to other functional food products such as artificial sweeteners and salt substitutes; (4) that the burden of determining breath-freshening ability would be on the manufacturer and not on FDA; (5) that there is a well-established and accepted scientific methodology for testing breath malodor (included in the petition); (6) that the underlying concept in reference amount issues is the amount customarily consumed; and (7) that the data conclusively establish that, for the specific product researched, the majority of consumers eat one mint per eating occasion to attain the same breath-freshening benefit they would attain by consuming one larger breath mint.

In addition, the agency received letters from two other manufacturers of breath mint products requesting a ''1 mint'' serving size. FDA received one letter and spoke with a manufacturer of breath mints that are even smaller (0.13 g each) than those discussed in the petition (Refs. 2 and 3). The letter indicated that under current regulations, the serving size for the company's product would need to be expressed as ''15 pieces (2 g).'' The manufacturer stated that the tablets are promoted as breath mints, that they have been specially formulated to be extremely potent, and that it is the manufacturer's intent that the consumer need only use one tablet per occasion to achieve fresh breath. The manufacturer objected to the 2-g reference amount because it felt it would be subject to unlimited liability if the serving size remains 15 tablets for its ''extremely potent'' breath mint product. The company requested that it be permitted to express the serving size as one piece. No data were submitted with the request.

The agency received another letter from a manufacturer of breath mints that are larger (0.67 g each) than those discussed in the petition (Ref. 4). This letter stated that, in accordance with current regulations, the serving size for the company's product is expressed as ''3 pieces (2 g).'' The manufacturer stated that the mints are characterized by strong flavor and are typically consumed one at a time. The manufacturer objected to being required to list their serving size as three mints if larger and smaller mints would be permitted to use a one mint serving size. The manufacturer stated that it would support a proposal to establish a one mint serving size for breath mints. No data were submitted in this letter.

III. Basis for the Proposed Action on Serving Size

A. Evaluation of the Appropriateness of the Current Serving Size Declaration on the Label of Small Breath Mints

As discussed in section I of this document, in the final rule for serving sizes (58 FR 2229 at 2297), data on large breath mints were used to establish the 2-g reference amount for the ''Hard candies, breath mints'' product category.

FDA has carefully reviewed the evidence (e.g., study design, results, conclusions) supporting the petitioner's request that FDA create a product category for small breath mints with a reference amount of 0.5 g (Refs. 5, 6, and 7). The analysis submitted with the petition was based on ''the number of pieces put into the mouth at one time.'' However, reference amounts are based on ''amounts customarily consumed per eating occasion.'' Therefore, FDA reanalyzed the data to estimate the number of mints customarily consumed at a single eating occasion. The number of pieces put into the mouth at one time may not always represent the number of pieces customarily consumed at a single eating occasion. For example, a person may eat 10 jelly beans within a few minutes but may only put one piece in his or her mouth at a time and finish each one before eating another. This situation would still represent 10 jelly beans eaten during a single eating occasion.

Based on the agency's reanalysis of the data, FDA determined that, when compared with larger breath mints, people typically eat more small breath mints at a single eating occasion. The agency calculated that the mean, median, and modal intakes in the petitioner's survey round to two mints customarily consumed per eating occasion. This is greater than the one mint reported by the petitioner, but much less than the serving size declaration of five breath mints currently required on the label. Therefore, the data suggest that serving sizes near 2 g are too large for small breath mint products.

B. Consideration of a Different Reference Amount for Breath Mints

Many of the issues raised by the petitioner and in comments objecting to the petition (e.g., marketing position, trademarked slogan, and established serving size declarations) are irrelevant with regard to determining the reference amount customarily consumed per eating occasion.

''Breath-freshening'' functionality is important in selecting the appropriate product category (e.g., ''Hard candies, breath mints'' as opposed to ''Hard candies, other''). However, neither the petition nor the comments demonstrated that ''breath freshening efficacy'' and ''breath malodor elimination'' are related to consumption. Therefore, the extent of breath freshening of these various products is immaterial in terms of establishing an appropriate reference amount for the product category ''Hard candies, breath mints.''

Based on the current reference amount of 2 g for the ''Hard candies, breath mints'' product category, the various breath mint products discussed with the agency would have the following serving sizes:

TABLE 1.—SERVING SIZES FOR BREATH MINTS

Large breath mints—	1 mint (2 g)
Medium breath mints– –	3 mints (2 g)
Small breath mints— ..	5 mints (2 g)
Very small breath mints—	15 mints (2 g)

In response to the petition, FDA has considered various options for the breath mint product category and the

advantages and disadvantages of the various approaches. The agency searched for a rationale that is applicable to all breath mint products and that would not penalize small manufacturers who cannot easily obtain supportive data.

Because consumption is the basis for establishing a reference amount, the objection in the opposing comments that nearly half of the users surveyed consumed two or more mints per occasion remains a valid concern. As stated earlier, FDA's reanalysis of the data on small breath mints suggests that the consumption per eating occasion is, in fact, closer to two mints than to one mint (Ref. 5).

However, FDA is not convinced that creating a separate category for small breath mints in Table 2 of § 101.12 (b) (21 CFR 101.12(b)), as suggested by the petitioner, is the most reasonable option for achieving appropriate serving sizes for labeling all of the different breath mint products on the market. The agency is reluctant to create a 0.5 g-reference amount for small breath mints (as requested by the petitioner) or a reference amount equivalent to ''2 pieces'' (as supported by the data). These options may not be appropriate for other breath mint products and could result in a proliferation of requests for additional product categories for other breath mints. This action could evolve into reference amounts that are brand dependent (e.g., separate reference amounts for each size or brand of breath mints) and would require each manufacturer to obtain independent data to demonstrate how their particular product is used.

The agency is not convinced by the data presented that there is justification for revising the current reference amount of 2 g because the majority of breath mint packages sold to consumers contain breath mints whose weight is closer to 2 g (the weight of large breath mints) than to any other value (Ref. 8). Furthermore, as discussed in section III.A of this document, the data available to the agency indicate that some people may consume more small breath mints than large breath mints at a single eating occasion, resulting in an amount consumed that is greater than the weight of an individual small breath mint. Accordingly, FDA tentatively concludes that there is not a sufficient basis for revising the current reference amount of ''2 g.''

However, the agency is concerned about the apparent inappropriateness of the resulting serving sizes on the labels of small and very small breath mints (e.g., 5 small breath mints or 15 very small breath mints per serving). The comments that the agency has received from manufacturers, as well as the limited consumption data available to FDA, all suggest that the products were designed to be consumed singly or in small numbers, and that consumers do, in fact, limit their consumption to such amounts.

Therefore, the agency is persuaded that it is worthwhile to consider requiring the serving size on the label of all breath mints to be declared as one mint to more accurately reflect consumption across the broad spectrum of breath mint sizes, rather than declaring the serving size in terms of the number of mints closest to the 2-g reference amount, an amount reflective of products at only one end of the spectrum. A way to accomplish this approach would be to revise Footnote 9 to Table 2 in § 101.12 to require the serving size declaration on the label of breath mints to be expressed as ''1 piece (____ g)'' similar to the current declaration of ice cream cones, eggs, and chewing gum but to keep 2 g as the reference amount.

This action would allow comparison of breath mints on a mint-to-mint basis and would more accurately reflect consumption of this type of product. A serving size declaration of ''1 mint (2 g)'' would continue to reflect the consumption data for the large breath mints that were the basis for the current reference amount. In addition, for the petitioner's small breath mints, a serving size declaration of ''1 mint (0.4 g)'' is closer to the amount consumed (i.e., 2 mints based on FDA's reanalysis) than a declaration of ''5 mints (2 g).''

Accordingly, while proposing to maintain a fixed value (2 g) as the reference amount, FDA is proposing to revise § 101.12, Table 2, Footnote 9 to state ''Label serving sizes for ice cream cones, eggs, and breath mints of all sizes will be 1 unit.'' Such action will allow for efficient enforcement of the act by maintaining one subcategory in Table 2 for all breath mints, yet it will prevent consumer confusion that could result from inappropriately high numbers of pieces specified for a serving on the nutrition label.

At the same time, by maintaining a fixed value (2 g) as the reference amount, this action provides for a consistent basis for nutrient content and health claims, although in all likelihood the reference amount will have little impact on most claims. For example, because the reference amount is small (i.e., 30 g or less or 2 tablespoons or less), products making ''low'' claims (e.g., ''low calorie'') must meet the claim criteria based not only on the amount of the nutrient per reference amount but also per 50 g of product. The per 50-g criterion will be the most difficult for breath mints to meet and will, therefore, be the determining factor. For ''free'' claims, products must meet the claim criteria based on the amount of the nutrient per serving size (one piece) and per reference amount (2 g). Thus, a ''calorie free'' claim would only be permitted on products containing less than 5 calories per breath mint and per 2 g of breath mints (e.g., in the case of small breath mints, the product would have to have less than 5 calories per five pieces, so a small breath mint with 1 1/2 calories per mint would not be ''calorie free'').

IV. Basis for the Proposed Action on Declaration of Calories

FDA's regulations permit a claim about the amount of a nutrient in a product (e.g., ''1 tablet has 5 calories'') provided that: (1) It is a factual statement that is not false or misleading; and (2) it does not in any way implicitly characterize the level of the nutrient as being high or low (§ 101.13(i)(3)). In addition, the amount claimed must be accompanied by a referral statement (e.g., ''See back panel for nutrition information'') (§ 101.13(g)). These claims may be based on the amount of the nutrient in a serving or unit of the product. To not be misleading, claims based on the amount of nutrient in a unit (e.g., one mint) must identify the unit if the serving size declared on the label is not one unit.

Under the agency's nutrition labeling regulations, products containing less than 5 calories per serving must either declare the calories to the nearest 5-calorie increment, i.e., as ''5 calories,'' or as ''0'' (§ 101.9(c)(1)). Accordingly, calorie values of 2.49 or less per serving would always be declared in the nutrition label as ''0,'' while values of 2.5 to 4.99 calories could be declared as ''0'' or rounded to ''5.'' FDA set the rounding rules because it concluded that the caloric contribution of foods could not be determined with sufficient accuracy to justify smaller increments (55 FR 29487 at 29503, July 19, 1990). In addition, FDA concluded that amounts of less than 5 calories per serving are trivial and of no physiological significance (56 FR at 60421 at 60438, November 27, 1991).

The agency is aware, however, that amount claims are being made under § 101.13(i)(3) on labels of breath mints stating that the mints have 1 1/2 calories, a specific amount that is not allowed to be declared on the nutrition label.

While the regulations do not specifically state that the quantitative

amount specified in an amount claim must be consistent with the amount declared on the nutrition label, the agency has stated its belief in the importance of consistency between nutrient content claims and information in the nutrition label to prevent consumer confusion (technical amendments published on August 18, 1993 (58 FR 44020 at 44024)). This expectation of consistency appears to have been shared by at least one comment who suggested that ''FDA should permit the use of amount and percentage statements to convey information regarding the calorie content per serving of food, consistent with the number of calories that appear on the nutrition panel'' (58 FR 2302 at 2309).

FDA still considers the difference between 0 and 5 calories to be insignificant. However, the agency does not consider it likely that consumers would be misled by a calorie declaration of less than 5 calories. Results of an FDA nutrition label format study found that consumers respond to the absolute size of numbers used to describe nutrient amounts. Subjects estimated the significance of all small numbers as small (Refs. 9 and 10).

Therefore, the agency tentatively concludes that consumers will interpret any specific calorie declaration of less than 5 calories as implying that the food has an insignificant amount of calories. To resolve the discrepancy of declaring 0 calories on the nutrition label and amounts such as 1, 1.5, or 2 calories in an amount claim elsewhere on the label and to allow manufacturers more flexibility in label statements, FDA is proposing to modify § 101.9(c)(1) to state that, if a manufacturer provides a claim about the amount of calories in a food for which a serving of a product contains less than 5 calories per serving, e.g., ''1 calorie per mint,'' the number of calories declared in the nutrition label shall be consistent with the amount declared in the claim. FDA is also proposing to amend § 101.9(c)(1) to allow the nutrition label on any product with less than 5 calories per serving to optionally declare the exact amount of calories in lieu of zero calories. This added flexibility will allow any products with less than 5 calories per serving to declare the exact amount of calories rather than just those products that make amount claims on the label.

V. Effective Date

The agency periodically establishes by final rule in the **Federal Register** uniform effective dates for compliance with food labeling requirements (see, e.g., the **Federal Register** of December 27, 1996 (61 FR 68145)). FDA proposes that any final rule that may issue based upon this proposal become effective in accordance with a uniform effective date for compliance with food labeling requirements, which is established by final rule in the **Federal Register** and which is not sooner than 1 year following publication of any final rule based upon this proposal. The final rule would apply to affected products initially introduced or initially delivered for introduction into interstate commerce on or after its effective date. However, FDA notes that it generally encourages industry to comply with new labeling regulations as quickly as feasible. Thus, when industry members voluntarily change their labels, it is appropriate that they respond to any new requirements that have been published as final regulations up to that time. On the other hand, if any industry members can foresee that the proposed effective date will create particular problems, they should bring these problems to the agency's attention in comments on this proposal.

VI. Environmental Impact

The agency has determined under 21 CFR 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Executive Order 12866 Analysis

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach which maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866.

This proposed rule will cause the labels of small breath mints to be revised. FDA estimates that there are 18 brands and 125 labels of breath mints of all sizes. Of those breath mints for which FDA has information regarding the size of the product, there are 4 firms producing 5 brands of small breath mints, or 30 distinct small breath mint labels. For breath mint products, the average administrative, redesign, and inventory disposal costs for a labeling change of this type, with a 1-year compliance period are $500 per label, or a total of $15,000.

The benefit of this proposed regulation is that manufacturers can provide a serving size that is more appropriate for small breath mints providing more accurate information to consumers.

VIII. Small Entity Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. FDA estimates that three of the firms producing small breath mints are small (under 500 employees). One of these small entities is the petitioner. FDA has received information from the other two small entities stating that they are in favor of granting the petition. Because FDA is providing these small entities with exactly what they requested, the agency concludes that this rule will not result in a significant impact on a substantial number of small entities.

IX. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Nutrition Labeling; Declaration of Caloric Amounts and Serving Sizes for Breath Mints.

Description: Section 403(q) of the act requires that the label or labeling of a food bear nutrition information, including information on the number of calories present in the product and the serving size and number of servings per container. FDA has issued regulations in § 101.9(c)(1) that require that the nutrition facts panel of the food label disclose the number of calories in the food. FDA has issued regulations in § 101.9(d)(3) that require that the nutrition facts panel disclose the serving size of the food product and the number of servings in each package.

The regulations set forth in this proposed rule would modify the rounding rules for calories in § 101.9(c)(1) to allow the voluntary declaration of caloric amounts of less than 5 in the nutrition label. The regulations would also require that the number of calories declared on the nutrition label of a food product be consistent with any claims about caloric content that are made in its labeling. As a result of this proposed rule, manufacturers and other producers of products that make claims that their products contain between 1 and 5 calories would be required to change the declaration of the amount of calories on the nutrition label. Finally, as a result of the proposed rule, manufacturers of small breath mints would be required, under § 101.9(b), to change the serving size disclosed on the labels of their products and, under § 101.9(c) and (d), the amounts and daily values for nutrients listed in the nutrition label for their products.

Description of Respondents: Persons and businesses, including small businesses.

TABLE 2.—ESTIMATED ADDITIONAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Total No. of Responses	Hours per Response	Total Hours	Total Operating Costs
101.9(b) and (c)(1)	4	30	1	30	$15,000

[1] There are no capital or maintenance costs associated with this collection of information.

The proposed modification of the rules for the declaration of the amount of calories and the proposed change of the label serving size on the nutrition facts panel would result in a one-time burden created by the need for firms to revise their labels. In addition to changing the statement of calories and the serving sizes, firms would have to recalculate the number of servings per container and any nutrient amounts and Daily Values affected by the change in serving size. As noted in section VII of this document, Executive Order 12866 Analysis, FDA is aware of only four firms that currently market small breath mints. These are the only firms that would be affected by this proposed rule. FDA estimates that there are approximately 30 labels for products marketed by these firms that would require revision because of this proposed rule. FDA estimates that these firms would require an average of 1 hour per label to comply with the requirements of a final rule based on this proposal. Further, as discussed in section VII of this document, Executive Order 12866 Analysis, the proposed rule would result in a one-time operating cost of $500 per label or a total estimated operating cost of $15,000.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection requirements of the proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 29, 1998, to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

X. Comments

Interested persons may, on or before March 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum to file, from Lori A. LeGault and Ellen M. Anderson, Center for Food Safety and Nutrition (CFSAN), FDA, August 28, 1997.

2. Letter to F. Edward Scarbrough, CFSAN, FDA, from Richard J. Litner, Nutrinfo Corp., August 24, 1994.

3. Memorandum of telephone conversation between Ellen M. Anderson, CFSAN, FDA, and Richard J. Litner and David Kiernan, Nutrinfo Corp., November 4, 1994.

4. Letter to F. Edward Scarbrough, CFSAN, FDA, from Sheryl A. Marcouiller, Kraft Foods, June 28, 1996.

5. Memorandum from Sara Fein, CFSAN, FDA, to Lynn McFerron, CFSAN, FDA, September 9, 1994.

6. Memorandum from Sara Fein, CFSAN, FDA, to Lori LeGault, CFSAN, FDA, February 5, 1996.

7. Memorandum to file from Lori A. LeGault and Ellen M. Anderson, CFSAN, FDA, August 28, 1997.

8. Memorandum to file from Thomas B. O'Brien, Mary M. Bender, and Ellen M. Anderson, CFAN, FDA, August 28, 1997.

9. Memorandum from Sara B. Fein, CFSAN, FDA, to Virginia Wilkening, CFSAN, FDA, May 13, 1997.

10. Levy, Alan S., Sara B. Fein, and Raymond E. Schucker, ''Performance Characteristics of Seven Nutrition Label Formats,'' *Journal of Public Policy and Marketing*, 15 (1)(Spring 1996): 1–15.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.9 is amended by revising paragraph (c)(1) introductory text to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed either as zero or as the exact amount. However, if a manufacturer provides a claim under § 101.13(i) about the amount of calories in a serving of a product containing less than 5 calories (e.g., ''1 calorie per mint''), the number of calories declared in the nutrition label shall be consistent with that declared in the amount claim (e.g., ''1''). Energy content per serving may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content.

* * * * *

3. Section 101.12 is amended in paragraph (b), Table 2, under the ''Sugars and Sweets'' category by revising the entry for ''Hard candies, breath mints'' and Footnote 9 to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3] [4]

Product category	Reference amount	Label Statement [5]
* *	* * *	* *
Sugars and Sweets:		
* *	* * *	* *
Hard candies, breath mints [9]	2 g	____ piece(s) (____ g)
* *	* * *	* *

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e, heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufactures are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

[6] Includes cakes that weigh 10 g or more per cubic inch.

[7] Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

[8] Includes cakes that weigh less than 4 g per cubic inch.

[9] Label serving size for ice cream cones, eggs, and breath mints of all sizes will be 1 unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be 1 unit.

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Dated: December 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–209463–82]

RIN 1545–AV82

Required Distributions From Qualified Plans and Individual Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains amendments to the existing proposed regulations under section 401(a)(9) that make changes to the rules that apply if a trust is named as a beneficiary of an employee's benefit under a retirement plan. These proposed regulations will affect administrators of, participants in, and beneficiaries of qualified plans, institutions which sponsor and individuals who administer individual retirement plans, individuals who use individual retirement plans, simplified employee pensions and SIMPLE Savings Plans for retirement income and beneficiaries of individual retirement plans; and employees for whom amounts are contributed to section 403(b) annuity contracts, custodial accounts, or retirement income accounts and beneficiaries of such contracts and accounts.

DATES: Written comments and requests for a public hearing must be received by March 30, 1998.

ADDRESSES: Send submissions to CC:DOM:CORP:R (REG–209463–82),