

In February 1996, Judy L. Carr petitioned the Commission to "initiate Rulemaking Proceedings to amend 16 CFR 1210, the *Safety Standard for Cigarette Lighters*, to include the Scripto® Tokai Aim 'n Flame™ disposable butane 'multi-purpose' lighter within the scope of that standard and its child resistant performance requirements." The petitioner provided information about eight incidents associated with the Aim 'n Flame™ lighter. One of the incidents involved the petitioner's child. Information about the other incidents was obtained through discovery in the petitioner's litigation with the product's manufacturer.

The Commission also was aware of 53 fires from January 1988 through October 1996 that were started by children under age 5 using multi-purpose lighters. These fires resulted in 10 deaths and 24 injuries. Based on this, and other relevant information, the Commission, on January 16, 1997 (62 FR 2327), commenced a rulemaking proceeding by publishing an ANPR under the Consumer Product Safety Act (CPSA) that could result in the promulgation of a rule mandating a performance standard for the child-resistance of the operating mechanism of multi-purpose lighters.

B. Statutory Procedure

Before adopting a CPSA standard, the Commission first must issue an ANPR as provided in section 9(a) of the CPSA, 15 U.S.C. 2058(a). If the Commission decides to continue the rulemaking proceeding after considering responses to the ANPR, the Commission must then publish the text of the proposed rule, along with a preliminary regulatory analysis, in accordance with section 9(c) of the CPSA, 15 U.S.C. 2058(c). If the Commission then wishes to issue a final rule, it must publish the text of the final rule and a final regulatory analysis that includes the elements stated in section 9(f)(2) of the CPSA, 15 U.S.C. 2058(f)(2). In addition, before issuing a final regulation, the Commission must make certain statutory findings concerning voluntary standards, the relationship of the costs and benefits of the rule, and the burden imposed by the regulation. CPSC § 9(f)(3), 15 U.S.C. 2058(f)(3).

Section 9(c) of the CPSA, 15 U.S.C. 2058(c), further provides that if the Commission continues the rulemaking by issuing a notice of proposed rulemaking, it must do so within 12 months after publication of the ANPR, or by January 16, 1998, unless the Commission extends the 12-month period for good cause. In that event, the Commission must send notice of the

extension to specified congressional committees, explaining the reasons for the extension and estimating the date by which the Commission anticipates the rulemaking will be completed. The Commission is required to publish notice of such extension, and the information submitted to Congress, in the **Federal Register**.

C. Ongoing Staff Work

In order to obtain the information necessary for the Commission to decide whether to issue a proposed rule, the staff has contracted for "baseline" testing of multi-purpose lighters. The purpose of this testing is to evaluate the potential benefits of any mandatory requirements by determining the proportion of children under 5 years of age that can operate the lighters. The testing is being conducted using panels of children. The staff is also evaluating the feasibility of mandatory child-resistant features on multi-purpose lighters and the potential costs of mandatory requirements.

D. Schedule for Publication of Notice of Proposed Rulemaking

The baseline testing is scheduled to be completed in March 1998. Shortly thereafter, the staff expects to complete a briefing package. The briefing package will (1) provide staff responses to the comments on the ANPR, (2) update the incident data, (3) report the results of the baseline testing, (4) include a draft preliminary regulatory analysis, and (5) discuss other technical work needed to address issues raised in the comments on the ANPR. It is anticipated that a notice of proposed rulemaking (NPR), if approved, would be published in the summer of 1998. If an NPR is published, a final rule could be issued during Fiscal Year 1999.

Extension of Time Period

Based on the foregoing, the Commission, for good cause, on December 23, 1997, voted to extend the period of time for issuance of a notice of proposed rulemaking for multi-purpose lighters until September 30, 1998. The Commission estimates that, if an NPR is issued by that date, the rulemaking could be concluded with the issuance of a final rule by September 30, 1999. The Commission notes, however, that if it is unable to make the findings required by the statute, the proceeding could be further extended or terminated.

Dated: December 31, 1997.

Todd A. Stevenson,

Deputy Director, Office of the Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 96P-0023 and 96P-0179]

Food Labeling; Serving Sizes; Reference Amounts for Candies

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 modify the product category "Sugars and Sweets: Hard candies, others" by adding "after-dinner mints, caramels, fondants (e.g., plain mints, candy corn), and liquid and powdered candies" as kinds of products included under the category, and a reference amount customarily consumed per eating occasion (reference amount) of 15 milliliters (mL) for liquid candies; create a new product category under "Sugars and Sweets," identified as "Chocolate-covered fondants (e.g., chocolate-covered creams, chocolate-covered mints), taffy, and plain toffee," with a reference amount of 30 grams (g); and clarify what kinds of candies belong to the "All other candies" product category by expanding the category name to include specific examples. This proposal is in response to two petitions and two letters submitted to the agency. The proposed changes are based on information provided in the letters and on analyses of the petitioners' data and of the most recent candy consumption data available from the U.S. Department of Agriculture's (USDA) 1994 and 1995 Continuing Survey of Food Intakes by Individuals (CSFII).

DATES: Written comments by March 24, 1998. See section V of this document for the proposed effective date of a final rule based on this document.

Written comments on the information collection requirements should be submitted by February 9, 1998.

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 requirements 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: Lori A. LeGault, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5483.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

In the **Federal Register** of July 19, 1990 (55 FR 29517 at 29530), FDA proposed standard serving sizes for 159 product categories based on the amount of food commonly consumed per eating occasion by infants, toddlers (children under 4 years of age), and the general population (persons 4 years of age or older). The agency proposed a standard serving size of 1/2 ounce (oz) for "Baking candies, chips, etc." and 1 1/2 oz for "Candies" (55 FR 29517 at 29532).

On November 8, 1990, before FDA issued a final rule on serving sizes, the President signed into law the Nutrition Labeling and Education Act of 1990 (hereinafter called the 1990 amendments). This statute amended section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) to require that virtually all foods under FDA's jurisdiction bear nutrition information that is based on a serving size that reflects the amount of food that is customarily consumed per eating occasion and that is expressed in a common household measure that is appropriate to the food (21 U.S.C. 343(q)(1)(A)(i), added to the act by section 2(a) of the 1990 amendments). The 1990 amendments also directed FDA to adopt regulations that establish standards for defining serving sizes (section 2(b)(1)(B) of the 1990 amendments).

In response to the 1990 amendments, FDA, among other actions, issued a reproposal on serving sizes (56 FR 60394, November 27, 1991). In this document, FDA proposed standards for deriving a serving size from the reference amount of a food customarily consumed per eating occasion (hereinafter referred to as reference amount). FDA also proposed reference amounts for 131 food product categories. Specifically, it proposed a reference amount of 15 g for "Baking candies (e.g., chips) and hard candies" and a reference amount of 40 g for "All

other candies" (56 FR 60394 at 60419). FDA analyzed USDA food consumption data from the 1977-1978 Nationwide Food Consumption Survey (NFCS) (Refs. 1 through 4) and the 1987-1988 NFCS (Ref. 5) and used these data as the primary basis for determining reference amounts (Ref. 6).

1. Hard Candies

The agency received several comments from the hard candy industry opposing the uniform 15-g reference amount for all hard candies (comment 124, 58 FR 2229 at 2266). The comments stated that the 15-g reference amount would result in the serving size being the entire package for breath mints or roll candies. The comments contended that breath mints and hard roll candies are consumed in much smaller quantities than other hard candies and should have separate smaller reference amounts.

After studying all comments and the data submitted, the agency was persuaded that breath mints, roll-type candies, and mini-size candies in dispenser-type packages should have separate reference amounts. Accordingly, in the final rule on serving sizes (58 FR 2229 at 2297, January 3, 1993) (hereinafter referred to as the serving size final rule), FDA divided hard candies into the following three product categories, each with its own reference amount: (1) Hard candies, breath mints - 2 g; (2) hard candies, roll-type and mini-size in dispenser-type packages - 5 g; and (3) hard candies, others - 15 g.

2. All Other Candies

FDA also received several comments on the proposal that opposed the 40-g reference amount for all other candies. Some of these comments recommended a uniform 1-oz reference amount to allow for fast and accurate nutrition comparisons of different candies (comment 125, 58 FR 2229 at 2267). One comment requested that FDA create a separate product category for specialty fine chocolates/pralines, with a reference amount of one piece, and others stated that the proposed reference amount was too large for "after dinner mints" and for fine bonbons (comment 126, 58 FR 2229 at 2268).

In the serving size final rule, FDA advised that the serving size on the product label is, by statute, an amount customarily consumed. None of the comments submitted food consumption data to show that the amounts customarily consumed of these candies differ from the proposed reference amount. Therefore, FDA rejected these requests and adopted the 40-g reference

amount for "All other candies" (58 FR 2229 at 2268).

B. Food Consumption Data Bases

The proposed and final rules on serving sizes (56 FR 60394 at 60403 and 58 FR 2229 at 2235) discussed FDA's use of food consumption data as the primary basis for establishing reference amounts. As stated in section I.A of this document, the agency based its values on data from national food consumption data bases, specifically the USDA 1977-1978 NFCS (Refs. 1 through 4) and the 1987-1988 NFCS (Ref. 5), that contained food intake data for individuals. These data were representative of the food consumption practices of the three age groups of interest (i.e., infants, toddlers, and the general population 4 years of age and older). The agency also used the 1985-1986 CSFII (Refs. 7 and 8) to confirm that apparent trends observed between the 1977-1978 NFCS data and the 1987-1988 NFCS data were not artifacts of the low response rate to the 1987-1988 survey. In the proposed rule on serving sizes (56 FR 60394 at 60403), the agency discussed its selection of these data bases and the advantages and disadvantages of the various sources of data. In the serving size final rule (58 FR 2229 at 2236), FDA responded to comments supporting and objecting to the data bases selected.

Since publication of the serving size final rule in 1993, USDA has made available data from the 1989-1991 CSFII and data for 1994 and 1995 from the 1994-1996 CSFII. The first 2 years of the 1994-1996 CSFII contain the most recent nationwide food consumption data available and have a large sample size and high response rate. The 1994 CSFII contains data on 5,589 individuals with 1-day records (80.1 percent response rate) and on 5,311 individuals with 2-day records (76.2 percent response rate) (Ref. 9). The 1995 CSFII contains data on 5,326 individuals with 1-day records (79.9 percent response rate) and on 5,072 individuals with 2-day records (76.1 percent response rate) (Ref. 10). Some differences in the CSFII 1994-1996, compared with earlier surveys, include: (1) A target population of noninstitutional individuals in all 50 States rather than the 48 contiguous States; (2) the collection of 2-nonconsecutive days of food intake through face-to-face interviews rather than 3-consecutive days of food intake using a 1-day recall and a 2-day record; (3) subsampling within households rather than the collection of information from all members of a household; and (4) tighter management control to minimize nonresponse.

FDA will use the most recent applicable data to resolve issues involving reference amounts that are raised in petitions or letters or that are identified by the agency.

C. The Petitions

1. Mint Candies

The Nutrition Research Group and representatives of Andes Candies, Inc., (the petitioners) met with FDA on October 27, 1995, to submit a petition (Docket No. 96P-0023) to the agency. The petition requested that FDA amend the "Sugars and Sweets" product category for "Hard candies, others" to read "Hard candies, mint wafers, and others," and that it change the reference amount for Andes mint wafers and similar products from 40 g to 15 g. The petition presented study data from an "in-home" consumption survey in support of a reference amount of 15 g for Andes mint wafer candies. In the survey, each of the 48 participating households received 2 pounds of test product (i.e., Andes Creme De Menthe Thins). Household members were asked to record each eating occasion for up to 2 weeks. The survey results consisted of 1,505 eating occasions, where the exact number of pieces eaten was recorded in a diary during the time of eating. The gram amounts were determined by multiplying the number of pieces eaten by the piece weight of 4.8 g. The study reported the mean (i.e., average) as 16.94 g, median (i.e., 50th percentile value) as 14.4 g, and mode (i.e., most frequently consumed amount) as 10 g for the amount consumed per eating occasion.

The petitioners also provided data from the 1989-1991 CSFII and the 1987-1988 NFCS on the reported eating occasions for food code 917-0540, "Chocolate, white (include summer coating, Andes Mint Wafers)." For the 1989-1991 CSFII, the data contained 23 eating occasions with consumption values reported as the weighted mean (9.34 g), median (10 g), and mode (10 g). For the 1987-1988 NFCS, the data contained 18 eating occasions with consumption values reported as the weighted mean (30.01 g), median (15 g), and mode (10 g). The petitioners stated that the product (i.e., Andes mint wafers) could not be identified in the 1977-1978 NFCS data.

At the October 27, 1995, meeting, FDA asked the petitioners whether candies other than "mint wafers" would fit into the requested product category and suggested that the petitioners provide examples of these candies. The agency also questioned the methodology by which the survey data were analyzed

because: (1) The total amount of candy provided to each household was fixed. Consequently, the reported amounts consumed for any "large eaters" who exhausted their fixed supply of candy were counted less, because their number of eating occasions was fewer, than smaller eaters whose candy supply lasted for more eating occasions. This fact suggests a bias toward smaller consumption values. (2) The reference amounts are based on the amount customarily consumed per eating occasion. Therefore, measuring each participant's intake for the same length of time is important so that each eating occasion is given the appropriate weight.

The petitioners agreed to reanalyze the data based only on the first 3 days of consumption to more closely conform with the design of the USDA food consumption surveys.

On January 18, 1996, the petitioners submitted an addendum containing the following information: (1) A list of 41 examples of mint candies (including hard candy mints) that they thought would fit in the requested product category. The examples included piece sizes and serving size label statements based on a 15-g reference amount. (2) A revision to rename the suggested product category as "Hard candies and mints, other" with a reference amount of 15 g. (3) Study data reanalyzed using only the first 3 days of each household's consumption. The 3-day data results showed 476 eating occasions and showed the mean (17.7 g), median (14.4 g), and mode (10 g).

The petitioners submitted a second addendum on October 10, 1996, containing data on candy consumption that were generated from the 1994 CSFII. The data analysis included both hard and soft individually-wrapped, small mint candies weighing 15 g or less per piece and "Mints, not further specified (NFS)." Hard candy mints that have reference amounts of 2 g (breath mints) and 5 g (roll-type and mini-size in dispensers) were excluded. Also excluded, however, were mints that weigh more than 15 g and mints that are usually not individually wrapped. The estimates were calculated for 39 eating occasions, and the weighted data showed the mean (13.91 g), median (15 g), and mode (15 g). The petitioners suggested that a possible description for this product category would be "Other hard candies and individually-wrapped small mints (15 g or less per piece)."

2. Candies Weighing 20 Grams or Less Per Piece

The Chocolate Manufacturers Association (CMA) and the National

Confectioners Association (NCA) jointly submitted a petition (Docket No. 96P-0179) to FDA on May 30, 1996, requesting that the agency amend the "Sugars and Sweets" product category by establishing a new 25-g reference amount for candies (other than hard candies or baking candies) weighing 20 g or less per piece. CMA and NCA presented combined data derived from two in-home consumption surveys (one for chocolate candies and one for nonchocolate candies). The surveys involved 12 types of small-piece (20 g or less) candy products that are sold either as individually-wrapped pieces (Hershey's Kisses (4.9 g); Andes Creme De Menthe Thins (4.8 g); Snickers Fun-Size Bars (20 g); Brach's Milk Maid Caramels (9.65 g); Starburst Fruit Chews (5 g); and Tootsie Roll Midgees (6.67 g)) or as unwrapped components of larger, bulk packages (Pangburn's Assorted Chocolates (17 g); Fannie May Kitchen Fresh Candies (16 g); Perugina Classic Collection Finest Assorted Chocolates (11.6 g); Farley's Candy Corn (1.47 g); Dae Julie Gummi Bears (2.22 g); and Farley's Jelly Beans (2.35 g)). The surveys did not consider hard candies or baking candies, which are already subject to product-specific reference amounts separate from the "All other candies" product category (§ 101.12(b) (21 CFR 101.12(b)), Table 2). It should be noted that the survey data provided for Andes Creme De Menthe Thins are the identical data submitted in support of the petition described in section I.C.1 of this document.

Each of the 652 households that participated in the surveys received 2 pounds of test product (i.e., one type of candy). Household members were asked to record each eating occasion and the exact number of pieces eaten for up to 2 weeks. The gram amounts were determined by multiplying the number of pieces eaten by the piece weight of the specific candy. The data consisted of 13,884 eating occasions with the mean (28.3 g), median (23.2 g), and mode (15 g). Based on FDA's request of Andes Candies, Inc., CMA and NCA also provided the data for the first 3 days of each household's consumption. These 3-day data showed 6,124 eating occasions with the mean (29.9 g), median (23.2 g), and mode (15 g).

CMA and NCA asserted that the subject products are typically consumed at a level significantly below 40 g, and that the data are strongly skewed toward lower levels of consumption. CMA and NCA also stated that the median value (i.e., 23.2 g) is the most appropriate measure of central tendency for consumption of candies weighing 20 g or less per piece, and that a way to

compensate for strongly skewed data is to remove extreme "outliers" and to include only data within 2 or 3 standard deviations from the mean. On this basis, for all eating occasions, CMA and NCA reported that the mean is reduced from 28.3 g to 26.1 g (data within 3 standard deviations from the mean) or to 24.1 g (data within 2 standard deviations from the mean); the median remains at 23.2 g.

CMA and NCA provided a supplement on July 22, 1996, noting that a small number of individuals in the previously mentioned surveys consumed very large amounts of the candy (up to 415 g) during a single eating occasion. These large consumption values raised the mean but did not otherwise affect the amounts of candy that most consumers ate per eating occasion, i.e., the large consumption values did not affect the median or mode. As mentioned in this petition and explained previously, if the relatively few extreme-upper-end consumers (i.e., outliers more than 3 standard deviations above the mean) are removed from the calculation, the mean value of candy consumed drops by several grams, and the median (as well as the mode) remains the same. CMA and NCA also emphasized that, while they provided calculations based not only on all data but also on data with outliers removed from the data set, they included all data in the petition (i.e., outliers had not been removed).

CMA and NCA submitted a second supplement on October 1, 1996, in response to a request from FDA for further explanation of the methods and rationale for eliminating outliers in evaluating the data contained in the petition. In addition to addressing the agency's request, the CMA and NCA cited further statistical support for recommending that, because the data were strongly skewed, the median value (23.2 g) was the best measure of central tendency.

D. Written Requests

1. Powdered Candy

After publication of the serving size final rule, two manufacturers submitted written requests asking the agency to classify powdered candies in the "Hard candies, others" product category with a reference amount of 15 g (Refs. 11 and 12). This type of product is frequently sold in clear or colored straws or small packets. Both manufacturers stated that they had no consumption data available but agreed that 15 g is a more reasonable reference amount for this type of candy than the 40-g reference amount for all other candies.

In written responses to both requests, FDA acknowledged that an appropriate reference amount for flavored and colored powdered candy had not been specifically included in the January 6, 1993, regulations. To enable the manufacturers to nutrition label their products, FDA stated that, until it adopted a reference amount, it would be unlikely to object to the use of a 15-g reference amount for powdered candy based on the information that the manufacturers had provided (Refs. 13 and 14). The agency also provided this suggested reference amount in its August 1993 publication, "Food Labeling QUESTIONS AND ANSWERS" (Ref. 15). However, FDA made clear that it intended to undertake notice and comment rulemaking to establish a reference amount for this product (Refs. 13 through 15).

2. Liquid Candy

One of the requests regarding powdered candy asked that the agency classify liquid candy in the "Hard candies, others" product category, with a reference amount of 15 mL (Ref. 11). This type of product is frequently sold in wax containers containing syrup or flavored liquid. Although the requester provided no consumption data, it stated that the syrup is very sweet, and that the 40-g reference amount for all other candies is unrealistic for this type of candy. In a written response, FDA acknowledged that an appropriate reference amount for liquid candies had not been specifically included in the January 6, 1993, regulations and stated that, to enable the manufacturer to nutrition label its product, given the information the manufacturer had provided, it did not intend to object to the use of a 15-mL reference amount for syrup-filled wax candies (Ref. 13). The agency also provided this suggested reference amount in its August 1993 publication, "Food Labeling QUESTIONS AND ANSWERS" (Ref. 15). Again, FDA stated that it intended to undertake notice and comment rulemaking to establish a reference amount for this product (Refs. 13 and 15).

II. Evaluation of the Petitioners' Data

FDA assessed the supporting evidence (e.g., study design, estimates, conclusions) submitted by Andes Candies, Inc., and the supporting evidence submitted by CMA and NCA (Ref. 16). As stated in section I.C.2 of this document, the consumption data provided in the Andes Candies petition are identical to the data provided by CMA and NCA for consumption of Andes Creme de Menthe Thins. Because

the survey data submitted by Andes Candies, Inc., are a subset of the larger survey data submitted by CMA and NCA, the following evaluation applies to both petitions.

First, each of the 12 candies surveyed by CMA and NCA was matched to a specific population profile based on an "appropriate age ratio and gender for users." The selection of which type of candy was sent to a given household was determined by whether the household fit the appropriate profile. If the households had been randomly assigned to receive one of the 12 candy products, then extraneous factors that might affect consumption would likely have been equally distributed over all households in the sample. However, random assignment was apparently not used. Thus, given that each of the 12 different candy products had its own distinct demographic profile of users, the research appears to be a series of 12 smaller surveys containing approximately 150 completed diaries each. Therefore, FDA questions whether the sample size for each of the 12 subsamples is large enough to be representative of the U.S. population or even of the typical consumers of the different candy products.

Other potential flaws in the surveys relate to the adequacy of the candy supply and the household size. To determine the amount customarily consumed per eating occasion, it is important that each participant has access to the same amount of candy during an equal period of time, so that the reported amounts consumed can be weighted properly. Even if the analysis is restricted to the first 3 days of consumption to be more comparable to the USDA food consumption surveys, unless: (1) The 2-pound allotment of candy provided to each participating household was a sufficient supply for the number of eaters, and (2) no household exhausted its supply within 3 days, there is a flaw in the design of the surveys. Upon closer analysis, the data revealed that five households reported eating more than the allotted 2 pounds (907.17 g) of candy during the first 3 days of the data collection. In addition, the amount of candy delivered to each participating household was not proportional to the household size. For example, in the 3-day data, the number of participants per household varied from one to eight. Clearly, 2 pounds of candy in a household with one consumer represents far more product per person than does 2 pounds in a household in which there are eight consumers.

Given the methodology questions stated above, the agency has concerns

about the reliability and validity of these data. However, FDA reanalyzed the first 3 days of the data and determined the mean, median, and modal values for the amounts consumed for each of the 12 types of candies (Ref. 16). The results of the reanalysis showed that the consumed amounts were not consistent over all 12 candies. Among the 12 types of candies, the reanalysis showed that the consumption values clustered around five intake amounts. The consumption values for: Andes Creme De Menthe Thins clustered around 15 g; Hershey's Kisses, Brach's Milk Maid Caramels, Starburst Fruit Chews, and Tootsie Roll Midgees clustered around 20 g; Perugina Classic Collection Finest Assorted Chocolates, Farley's Candy Corn, Dae Julie Gummi Bears, and Farley's Jelly Beans clustered around 25 g; Pangburn's Assorted Chocolates and Fanny May Kitchen Fresh Candies clustered around 35 g; and Snickers Fun-Size Bars clustered around 40 g.

III. Evaluation of the Appropriateness of the 40-Gram Reference Amount

As discussed in section I.A of this document and in reference 2 to the proposed and final rules on serving sizes (Ref. 6), FDA determined in 1991 and 1993 that the food consumption data for candies other than hard candies and baking candies supported a 40-g reference amount. The data analysis encompassed a large variety of candy products, representative of 70 candy food codes from the 1977-1978 NFCS and 107 candy food codes from the 1987-1988 NFCS. Because data submitted in both petitions that are the subject of this document suggest that some types of candies may customarily be consumed in amounts significantly different than 40 g, FDA analyzed data from the 1994 and 1995 CSFII, the most recent nationwide candy consumption data available to the agency, to decide whether a change in the reference amount for some types of candies is warranted.

First, the agency identified the candy food codes in the 1994 and 1995 CSFII data base that were reflective of the candies specified in the petitions. FDA combined the candies with like characteristics and categorized the food codes into the following eight candy groups: (1) Plain chocolate candies; (2) white chocolate (includes summer coating, Andes Mint Wafers); (3) caramels; (4) candy bars; (5) taffy/toffee, plain; (6) fondants, plain; (7) fondants, chocolate-covered; and (8) gel/jellied candies (Ref. 17).

Next, FDA calculated the consumption amounts for each of the

eight groups. Based on the general principles that FDA considered in developing the reference amounts and the procedures that FDA used to apply these principles, described in the 1991 proposed rule on serving sizes (56 FR 60394 at 60402 through 60406) and in reference 2 to the proposed and final rules on serving sizes (Ref. 6), the data revealed that the eight groups resolved into three groupings. The amount consumed for: (1) White chocolate (includes summer coating, Andes Mint Wafers), caramels, and plain fondants reflected a reference amount of 15 g (equivalent to 0.5 oz), rather than 40 g; (2) chocolate-covered fondants, taffy, and plain toffee reflected a reference amount of 30 g (equivalent to 1 oz), rather than 40 g; and (3) all the remaining candy types (i.e., plain chocolate candies, candy bars, and gel/jellied candies) reflected a reference amount of 40 g (equivalent to 1.5 oz), which is consistent with the current 40-g reference amount for "All other candies" (see Ref. 17 for more detailed description and data).

The agency recognizes that the 1994 and 1995 CSFII contain some specific candy subcodes and measure codes, making it possible to identify more candies by their brand name and piece size. However, in most cases, the "n" value (i.e., number of eating occasions) for a specific subcode is too small to give a reliable estimate of the customarily consumed amount (Ref. 17). Additionally, the act has directed the agency to establish uniform serving sizes. Therefore, the same food should have the same reference amount regardless of its shape, size, or type of packaging (e.g., individually wrapped). Accordingly, it is the amount customarily consumed per eating occasion for the type of candy that determines the reference amount, not the specific size, shape, or weight of the candy.

IV. Proposed Action

A. Division of "All Other Candies" Product Category

Because the consumption data for certain candies (i.e., Andes Mint Wafers, caramels, fondants) support a 15-g reference amount (Ref. 17), and because of the agency's desire to simplify the product category description, the agency is proposing to include "after-dinner mints, caramels, and fondants (e.g., plain mints, candy corn)" in the same product category as "Hard candies, others" in § 101.12(b), Table 2, and to revise the name of the product category to reflect this change. It should be noted that this proposal would place mint

wafers consisting of chocolate flavored confectionary coating rather than chocolate that complies with the standard in 21 CFR 163.111, such as Andes Creme De Menthe Thins, in this "Hard candies, others" product category.

Because the consumption data for certain candies (i.e., chocolate-covered fondants, taffy, and plain toffee) support a 30-g reference amount (Ref. 17), the agency is proposing to establish a new product category of candies in § 101.12(b), Table 2, under "Sugars and Sweets," identified as "Chocolate-covered fondants (e.g., chocolate-covered creams, chocolate-covered mints), taffy, and plain toffee" with a reference amount of "30 g."

In accordance with § 101.12(h)(11), the agency also analyzed candy consumption from the 1994 and 1995 CSFII using the food codes for all other candies excluding those that were shown to support a 15-g or 30-g reference amount as stated previously (Ref. 17). The resulting data were consistent and continue to support the 40-g reference amount for "All other candies." To clarify the types of candy that are included in the "All other candies" product category, the agency is proposing, in § 101.12(b), Table 2, to expand the name of the product category to "All other candies (e.g., candy bars, chocolate candies, fudge, licorice, gumdrops, nut or raisin candies)" and to retain the reference amount of "40 g."

B. Powdered Candy

As stated in section I.D.1 of this document, a 15-g reference amount has been used for powdered candy since 1993. Furthermore, powdered candy products (e.g., Pixy Stix, Space Dust) are included as hard candies in the NFCS and CSFII data bases (Refs. 5 and 7 through 10), and FDA has established a reference amount of 15 g for "Hard candies, others" (§ 101.12(b), Table 2) based on its consideration of these data bases. The agency is, therefore, proposing to include "powdered candy" in the same product category with other hard candies in § 101.12(b), Table 2, and to revise the name of the product category to reflect this change.

C. Liquid Candy

As stated in section I.D.2 of this document, a 15-mL reference amount has been used for liquid candy since 1993. Data from the 1994 and 1995 CSFII showed only one eating occasion for liquid-filled waxed candy, and the amount consumed was shown as 23 g. One eating occasion is inadequate to represent the amount customarily

consumed for the population ages 4 years and above and therefore is inadequate to use as the primary basis for determining the reference amount. No data were reported for consumption of liquid candy in the previous USDA surveys.

The manufacturer who submitted the original request, as discussed in section I.D.2 of this document, included some samples of the syrup-filled wax candy with the submission. The package sizes submitted included the following: (1) 1/2 fluid (fl) oz (14 mL) package containing five wax containers, about 2.8 mL per container; (2) 1/2 fl oz (20 mL) package containing five wax bottle containers, about 4 mL per bottle; (3) a case of 20 wax bottle containers with a net contents of 2 1/2 fl oz (80 mL), about 4 mL per bottle; and (4) large, single-wrapped wax figures containing 3/4 fl oz (22.5 mL) or 1/2 fl oz (15 mL) each. Additionally, the requester stated that because the syrup is so sweet, it is unlikely that more than four or five of the small containers or more than one of the largest containers would be consumed at a single eating occasion.

These five package sizes suggested to the agency a reference amount of 15 mL to 25 mL. The agency then applied the general principles it uses to arrive at a reference amount to these values.

FDA described the general principles that it followed in expressing the reference amounts § 101.12(b) in the proposed and final rules on serving sizes (56 FR 60394 at 60406; 58 FR 2229 at 2238). FDA expressed reference amounts for fluids in milliliters. It expressed reference amounts for other foods, to the extent possible, in grams. As explained further in comment 21 of the final rule on serving sizes (58 FR 2229 at 2238), "The act requires that serving sizes be declared in common household measures, and therefore, those measures must drive the reference amounts * * *. Thus, it is important to adjust the reference amounts to be in metric amounts that convert to useful, whole number household measures rather than rounded metric units." Based on these principles, considering the packaging information that the manufacturer provided as stated above, and in the interest of minimizing the number of product categories, FDA has tentatively determined that 15 mL (equivalent to the whole number household measure of 1 tablespoon (§ 101.9(b)(5)(viii)) (21 CFR 101.9(b)(5)(viii)) is the most reasonable reference amount for liquid candies. FDA requests comments on this tentative determination.

The agency has become aware, through conversations and informal

investigations in the marketplace, of two other forms of liquid candies: (1) Clear or colored straws containing syrups and flavored honeys, and (2) bottles with bubble wands containing liquid candy that can be blown into bubbles before consuming. Based on the proposed reference amount of 15 mL, the appropriate serving sizes for these liquid candies would be "___ straws (___ mL)" for syrup or flavored honey in straws and "1 tablespoon (15 mL)" for liquid candy in bottles. Additional clarifying language could be provided for liquid candy that is to be blown into bubbles before consuming, e.g., "1 tablespoon (15 mL) (makes ___ bubbles)," with the blank to be filled in with a number (§ 101.9(b)(7)(v)). FDA would consider any bottle of liquid candy that contains less than 30 mL to be a single-serving container (§ 101.9(b)(6)).

Considering all of the information that is available to the agency, as stated previously, FDA is proposing to include "liquid candy" with a reference amount of "15 mL" in the same product category with other hard candies in § 101.12(b), Table 2, to revise the name of the product category, and to add the reference amount to reflect this change.

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 it may issue based on this proposal become effective in accordance with a uniform effective date for compliance with food labeling requirements, which is no sooner than 1 year following publication of the final rule. 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 25.30(k) and 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 some manufacturers to revise the serving size and corresponding nutrition labeling information on product labels for after-dinner mints, caramels, fondants, taffy, and plain toffee. FDA estimates that there are at least 116 firms producing candy products of the type covered by this proposed rulemaking. These manufacturers produce 730 labels that may be revised as a result of this rule. The specific costs of a labeling change are a function of the type of printing process used, the type of label used, the complexity of the label change, average label inventory, and length of the compliance period. On average, the administrative, redesign, and inventory disposal costs for a labeling change of this type, with a 1-year compliance period are \$500 per product, or a total of \$365,000.

The benefit of this proposed regulation is that because manufacturers will provide information on a serving size that is more appropriate for particular types of candy, product labels will provide more accurate information to consumers.

VIII. Small Entity Analysis

FDA has examined the economic implications of this 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 FDA concludes that this proposed rule will have a significant impact on a substantial number of small entities.

A. Estimate and Description of the 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 (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For candies, a business is considered small if it has fewer than 500 employees.

FDA estimates that 99 of the firms producing after-dinner mints, caramels, fondants, taffy, and plain toffee are small. The small firms that FDA has identified produce between 1 and 23 product labels (average equals 4 labels) that might be relabeled as a result of this rule.

B. Description of the Impacts

The cost of this rule per small firm will be between \$500 (\$500 multiplied by 1 product) and \$11,500 (\$500 multiplied by 23 products) with the average cost per small firm of \$2,000. FDA considers these costs to be significant to a small entity. Under the Regulatory Flexibility Act (5 U.S.C. 605), the agency concludes that this proposed rule will have a significant impact on a substantial number of small entities.

C. Compliance Requirements and Necessary Skills

The Regulatory Flexibility Act also requires agencies to describe the projected reporting, recordkeeping, and other compliance requirements of the rule and the type of professional skills necessary for preparation of the report or record. Manufacturers of after-dinner mints, caramels, fondants, taffy, and plain toffee will be required to amend their labels to reflect the new serving size. Manufacturers must recalculate the reported levels of nutrients in the foods based on the new serving size. No further analyses are required, only that the reported amounts are based on the correct serving size.

D. Alternatives

FDA has examined the following alternatives to the proposed action that could minimize the significant economic impact on small entities consistent with stated objectives.

1. Exempt Small Entities

The agency has published an exemption from mandatory nutrition labeling for low-volume food products of small businesses in § 101.9(j)(18) (59 FR 11872, March 14, 1994). As of May 1997, § 101.9(j)(18) applies to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 100,000 units, produced by firms with fewer than 100 employees. To the extent that after-dinner mints, caramels, fondants, taffy, and plain toffee are eligible for this exemption, they will not require relabeling as a result of this rule. However, if the products are nutritionally labeled either because the label contains nutrient content claims, or because the manufacturer has voluntarily labeled the product, then the nutrition facts panel must be correct and the label must be changed. FDA is uncertain of how many products, if any, can or will take advantage of this option.

2. Lengthen the Compliance Period

FDA also considered the option of providing small entities with a longer compliance period. If finalized, labels must be changed by the appropriate uniform compliance date. Depending on when the final rule publishes, firms will have as little as 1 year or as much as 2 years to complete labeling changes. Longer compliance periods typically result in lower costs because firms can combine mandated label changes with planned changes and because firms have more opportunity to use up existing labels. A 2-year compliance period would reduce costs to \$300 per firm.

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 the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Labeling; Serving Sizes; Reference Amounts for Candies.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear information that provides the serving size that is appropriate to the food and the number of servings per container. FDA has issued regulations in § 101.9(d)(3) that require that the nutrition facts panel on the label of a food disclose the serving size of the food and the number of servings per container. FDA has also issued regulations in § 101.9(b) that provide that the serving size declared on a food label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" that appear in § 101.12(b).

The regulations set forth in this proposed rule would revise the reference amount that is used for determining the serving size for after-dinner mints, caramels, fondants, taffy, and plain toffee. As a result, manufacturers and other producers of these products would be required to change the serving sizes, number of servings per container, and levels of nutrients per serving disclosed in the nutrition facts panel of their products.

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

TABLE 1.—ESTIMATED ADDITIONAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Total No. of Responses	Hours per Response	Total Hours	Total Operating Costs
101.12(b)	116	730	1	730	\$365,000

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

The proposed change in the reference amount for after-dinner mints, caramels, fondants, taffy, and plain toffee would result in a one-time burden created by the need for firms to revise the labels for their products. In addition to changing the serving size, firms would have to recalculate the number of servings per container and the levels of nutrients per serving based on the new serving size. As noted in section VII of this document, in the Executive Order 12866 analysis, FDA estimates that there are at least 116 firms producing candy products of the type affected by this proposed rulemaking. FDA estimates that these firms would require an average of 1 hour per product to comply with the requirements of a final rule based on this proposal. Further, as noted in section VII of this document, in the Executive Order 12866 analysis, the proposed rule would result in a one-time operating cost of \$365,000.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection requirements of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by February 9, 1998, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

X. Comments

Interested persons may, on or before March 24, 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 numbers 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. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Spring Quarter 1977–1978, accession no. PB80–190218INC, National Technical Information Service, Springfield, VA, 1980.

2. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Summer Quarter 1977–1978, accession no. PB80–197429INC, National Technical Information Service, Springfield, VA, 1980.

3. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Fall Quarter 1977–1978, accession no. PB80–200223INC, National Technical Information Service, Springfield, VA, 1980.

4. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Winter Quarter 1977–1978, accession no. PB81–118853INC, National Technical Information Service, Springfield, VA, 1981.

5. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual Intake—1987–1988, accession no. PB90–504044INC, National Technical Information Service, Springfield, VA, 1990.

6. LeGault, Lori A., Memo to file, "Background Documentation for Determining the Reference Amounts Customarily Consumed per Eating Occasion (Reference Amounts) for Candies," CFSAN, FDA, Washington, DC, August 13, 1997.

7. U.S. Department of Agriculture, Continuing Survey of Food Intakes by Individuals: Four Days Food Intake for Women and Their Children 1–5, 1985, accession no. PB88–201249INC, National Technical Information Service, Springfield, VA, 1988.

8. U.S. Department of Agriculture, Continuing Survey of Food Intakes by Individuals: Four Days Food Intake for Women 19–50, Children 1–5, 1986, accession no. PB89–154355INC, National Technical Information Service, Springfield, VA, 1989.

9. U.S. Department of Agriculture, Continuing Survey of Food Intakes by Individuals, 1994, accession nos. PB96–500095INC (Magnetic Tape) and PB96–501010INC (CD-ROM), National Technical Information Service, Springfield, VA, 1996.

10. U.S. Department of Agriculture, Continuing Survey of Food Intakes by

Individuals, 1995, accession nos. PB97–500771INC (Magnetic Tape) and PB97–500789INC (CD-ROM), National Technical Information Service, Springfield, VA, 1997.

11. Knupfer, David, W & F Products Inc., letter to FDA, March 31, 1993.

12. Mercurio, Kenneth C., Nestle USA, Inc., letter to FDA, May 11, 1993.

13. Saltsman, Joyce J., FDA, letter to David Knupfer, W & F Products, August 26, 1993.

14. Saltsman, Joyce J., FDA, letter to Kenneth C. Mercurio, Nestle USA, Inc., August 11, 1993.

15. U.S. Department of Health and Human Services, "Food Labeling QUESTIONS AND ANSWERS," Food and Drug Administration, pp. 32–33, Washington, DC, August 1993.

16. Heaton, Alan W., Comments on Consumer Research Submitted to FDA in Two Petitions, CFSAN, FDA, March 25, 1997.

17. LeGault, Lori A., Memo to file, "Documentation Supporting the Proposed Changes to the Reference Amounts Customarily Consumed per Eating Occasion (Reference Amounts) for Candies," CFSAN, FDA, Washington, DC, August 14, 1997.

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 101.12 is amended in paragraph (b), Table 2, under the "Product Category" column under "Sugars and Sweets" by revising the entry for "Hard candies, others," by adding a new candy subcategory, and by revising the entry for "All other candies" 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, others; after-dinner mints, caramels, fondants (e.g., plain mints, candy corn), liquid and powdered candies	15 mL for liquid candies; 15 g for all others	___ piece(s) (___ g) for large pieces; ___ tbsp(s) (___ g) for small pieces; ___ straw(s) (___ g) for powdered candies; ___ wax bottle(s) (___ mL) for liquid candies; 1/2 oz (14 g/ visual unit of measure) for bulk products
Chocolate-covered fondants (e.g., chocolate-covered creams, chocolate-covered mints), taffy, and plain toffee	30 g	___ piece(s) (___ g); 1 oz (28 g/ visual unit of measure) for bulk products
All other candies (e.g., candy bars, chocolate candies, fudge, licorice, gumdrops, nut or raisin candies)	40 g	___ piece(s) (___ g); 1 1/2 oz (42 g/ visual unit of measure) for bulk products
* * * * *	* * * *	* * * *

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 Manufacturers 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).

* * * * *

Dated: December 31, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 98–375 Filed 1–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–209276–87]

RIN 1545–AV32

Abatement of Interest

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the abatement of interest attributable to unreasonable errors or delays by an officer or employee of the IRS in performing a ministerial or managerial act. The proposed regulations reflect changes to the law made by the Tax

Reform Act of 1986 and the Taxpayer Bill of Rights 2. The proposed regulations affect both taxpayers requesting abatement of certain interest and IRS personnel responsible for administering the abatement provisions.

DATES: Written comments and requests for a hearing must be received by April 8, 1998.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–209276–87), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–209276–87), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington DC. Alternatively, taxpayers may submit comments electronically via the INTERNET by selecting the “Tax Regs” option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/prod/tax_regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, David Auclair, (202) 622–4910 (not a toll-free number). Concerning submissions,

Michael Slaughter, (202) 622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Procedure and Administration Regulations (26 CFR Part 301) relating to the abatement of interest attributable to unreasonable errors or delays by an officer or employee of the IRS under section 6404(e)(1) of the Internal Revenue Code. Section 6404(e)(1) was enacted by section 1563(a) of the Tax Reform Act of 1986 (Pub. L. 99–514, 100 Stat. 2762 (1986)) (1986 Act) and amended by section 301 of the Taxpayer Bill of Rights 2 (Pub. L. 104–168, 110 Stat. 1452 (1996)) (TBOR2).

As enacted by the 1986 Act, section 6404(e)(1) provided that the IRS may abate interest attributable to any error or delay by an officer or employee of the IRS (acting in an official capacity) in performing a ministerial act. The legislative history accompanying the Act provided,

The committee intends that the term “ministerial act” be limited to nondiscretionary acts where all of the