retired, but in no event may stock be retired below the institution's minimum stock purchase requirements for the interest retained.

(iv) If an institution repurchases a loan on which the stock has been retired, the borrower shall be required to repurchase stock in the amount of the minimum stock purchase requirement.

(2) *Loans sold into a secondary market.* An institution's bylaws may provide that all outstanding voting stock held by a borrower with respect to a loan shall be retired when the loan is sold into a secondary market.

(d) *Applicability.* In the case of a loan sold into a secondary market under title VIII of the Act, paragraphs (b)(1) and (c)(2) of this section apply regardless of whether the institution retains a subordinated participation interest in a loan or pool of loans or contributes to a cash reserve.

§ 614.4336 Borrower rights in connection with loan sales.

(a) *Loan sales to Farm Credit System institutions.* Loans made by qualified lenders (as defined in section 4.14A(a)(6) of the Act) and interests in such loans that are sold to other qualified lenders are subject to the borrower rights provisions of title IV of the Act.

(b) *Loans designated for sale into a secondary market.* (1) Except as provided in paragraph (b)(2) of this section, the borrower rights provisions of sections 4.14, 4.14A, 4.14B, 4.14C, 4.14D, and 4.36 of the Act do not apply to a loan made on or after February 10, 1996, that is designated for sale into a secondary market at the time it is made.

(2) If a loan designated for sale under paragraph (b)(1) of this section is not sold into a secondary market during the 180-day period that begins on the date of designation, the borrower rights provisions specified as inapplicable pursuant to paragraph (b)(1) of this section shall apply, *provided that* if the loan is subsequently sold into a secondary market, the borrower rights specified in paragraph (b)(1) of this section become inapplicable beginning on the date of the subsequent sale.

(c) *Other loan sales.* (1) Except for loans sold to another Farm Credit institution or designated for sale into a secondary market, a qualified lender must comply with one of the following two requirements before selling a loan or interest in a loan that is subject to the borrower rights provisions of title IV of the Act:

(i) Include provisions in the contract with the borrower, or a written modification thereto, that ensure that the purchaser of the loan will be obligated to accord the borrower the same rights qualified lenders must provide under the Act; or

(ii) Obtain from the borrower a signed written consent to the sale that explicitly states that the borrower relinquishes the statutory borrower rights. The consent to the loan sale and the relinquishment of the borrower rights shall have no effect until the loan is actually sold and shall be ineffective in the event that the lender or any other Farm Credit System institution repurchases the loan or any interest therein.

(2) Before obtaining the borrower's consent to the sale of the loan and the relinquishment of borrower rights pursuant to paragraph (c)(1)(ii) of this section, the lending institution shall disclose in writing to the borrower:

(i) A full and complete description of the statutory rights that the borrower is asked to relinquish;

(ii) Any changes in the loan terms or conditions that will occur if the loan is not sold; and

(iii) The fact that the relinquishment of the statutory borrower rights will not become effective unless the loan is actually sold and shall become ineffective in the event that the lender or any other Farm Credit System institution repurchases the loan or any interest therein.

(3) The making of a loan may not be conditioned on the borrower's consent to its sale and relinquishment of statutory borrower rights.

Subpart K—Disclosure of Loan Information

§ 614.4367 [Amended]

3. Section 614.4367 is amended by removing paragraph (b) and redesignating paragraphs (c) through (e) as paragraphs (b) through (d).

Dated: November 24, 1997.

Nan P. Mitchem,

Acting Secretary, Farm Credit Administration Board.

[FR Doc. 97–31569 Filed 12–1–97; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 93P–0448]

Food Labeling; Serving Sizes; Reference Amount for Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' from a weight-based reference amount of 1 gram (g) to a volume-based reference amount of 1/4 teaspoon (tsp). This action is necessary to provide consistency with the agency's criteria for determining volume-based versus weight-based reference amounts for all product categories.

DATES: Effective January 1, 2000. This regulation applies to all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin January 2, 1998. Written comments on the information collection provisions should be submitted by January 2, 1998.

ADDRESSES: 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.

[i] Pub. L. 104–105 (February 10, 1996).

[ii] Generally, for each loan made by a qualified lender, a borrower is subject to minimum stock purchase requirements of 2 percent of the loan or $1,000, whichever is less. The borrower rights provisions of the Act impose certain disclosure and other obligations on lenders.

[iii] The specific borrower rights under the Act that are affected by the section 4.14A definitional change include reconsideration of actions (sec. 4.14), restructuring distressed loans (sec. 4.14A), effect of restructuring on borrower stock (sec. 4.14B), review of restructuring denials (sec. 4.14C), protection of borrowers who meet all loan obligations (sec. 4.14D), and right of first refusal (sec. 4.36).

As enacted, the language of section 208 of the 1996 Act amending the definition of ''loan'' leaves no doubt that Congress intended to include the section 4.36 borrower's right of first refusal among the borrower rights that become inapplicable when a loan is designated for sale into a secondary market. This is consistent with section 8.9(a) of the Act, which specifically exempts loans pooled under title VIII from section 4.36 borrower rights. However, section 208 of the 1996 Act did not amend the introductory paragraph of section 4.14A(a), which limits the applicability of the section's definitions to those ''used in this part [C of title IV].'' Since section 4.36 is located in part G (''Miscellaneous'') of title IV, it could technically be argued that the amended definition of ''loan'' does not apply to section 4.36. Notwithstanding this apparent drafting inconsistency, the FCA believes Congressional intent is clear and interprets the 1996 Act to exempt loans designated for sale into a secondary market from the section 4.36 borrower's right of first refusal.

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

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, Congress passed the Nutrition Labeling and Education Act (the 1990 amendments). This statute amended the Federal Food, Drug, and Cosmetic Act (the act) in section 403(q)(1)(A)(i) to require that virtually all foods bear nutrition information that is based on a serving size that reflects the amount of food that is customarily consumed and that is expressed in a common household measure 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 new law also directed FDA to adopt regulations that establish standards to define serving sizes (section 2(b)(1)(B) of the 1990 amendments).

After extensive notice-and-comment rulemaking, the agency published final rules implementing the 1990 amendments. In part, these rules established ''reference amounts customarily consumed per eating occasion'' (reference amounts) for use by industry as the basis for serving sizes for most foods. With regard to salt products, the agency concluded that 1 g was the appropriate reference amount for ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' (58 FR 2229 at 2297, January 6, 1993).

In addition, in discussing a different food category, FDA outlined the circumstances in which a weight-based reference amount would not adequately reflect the amount of food customarily consumed per eating occasion (Comment 20, 58 FR 2229 at 2238). The agency stated that weight-based reference amounts are not appropriate when foods within a product category vary considerably in density, i.e., there is a density difference of 25 percent or more among the products in the category (see § 101.12(e) (21 CFR 101.12(e))), and when the customarily consumed amounts for different products are more uniform when expressed in volume than in weight.

B. Petition to Modify the Reference Amount for Salt Products

In November of 1993, FDA received a petition requesting that it change the reference amount for salt from a weight-based reference amount of ''1 g'' to a density-adjusted reference amount to be listed as ''x g - 1/4 tsp.'' The petition included the results of a consumer study of consumption patterns of regular salt and low-density salt and analytical data comparing the physical properties (including density) of regular salt and low-density salt.

In response to a request from the agency, the petitioner submitted supplemental materials consisting of information regarding the protocol, data tabulation, and results of the consumer study it had submitted, including an independent evaluation of the results and conclusions.

FDA received one comment requesting that the agency reject the petition. The comment argued against granting the petition, questioned the consumer study data, and disagreed with the results and conclusions contained in the petition. The agency received comments from the petitioner that responded to the arguments presented in this comment.

After reviewing the information in the petition, the supplemental submission, and the comments, FDA determined that the petitioner had made a prima-facie case that a volume-based reference amount of 1/4 tsp for salt is more appropriate than the weight-based reference amount of 1 g that FDA adopted in 1993. Therefore, in accordance with 21 CFR 10.30(e)(2)(i), in the **Federal Register** of July 21, 1995 (60 FR 37616), FDA issued a proposed rule (hereinafter referred to as ''the proposed rule on salt products'') to change the reference amount for ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' from a weight-based reference amount of ''1 g'' to a volume-based reference amount of ''1/4 tsp.'' The agency requested comments on whether low-density salt products should be required to disclose clearly that they contain more air than conventional or regular salt products, and, if so, on what kind of descriptive terms would convey this information in a manner that is clear and nonmisleading for consumers.

This final rule responds to the comments FDA received in response to the proposed rule on salt products.

II. Review of Comments

FDA received and reviewed four responses to the proposed rule on salt products, each of which contained one or more comments. Two responses were received before and two after the close of the comment period. The two late comments discussed data and reiterated arguments contained in other comments.

A. Consumer Study of Consumption Patterns of Regular Versus Low-Density Salt

1. One comment noted that the original questionnaires from the consumer study submitted by the petitioner were no longer available, so an independent assessment of the data is no longer possible. The comment objected to using results and relying on conclusions that were based on summaries of the questionnaires.

Before acting on the petition, FDA specifically requested and received additional study data and summary tables that were not contained in the original petition (Docket 93P–0448/REF 1) [1]. The agency reviewed the study data and assessed the quality of the study design and the independent verification process. The agency tentatively concluded that the consumer research was a reasonably well-controlled experiment that met the scientific standards for the type of studies that can be used to determine household salt consumption [2] (Ref. 1).

The study was conducted in 1982 by an independent company (Ref. 1). Furthermore, the study results were authenticated by a separate marketing consulting firm and by an independent consultant. Section 101.12(h) does not require submission of raw data questionnaires for serving size petitions. The agency is satisfied with these salt consumption data and results because the data were independently gathered and compiled, and the study results were independently verified. The comment presented no basis for questioning the work done on the study.

The agency concludes that the absence of the original questionnaires is not significant, and that it is appropriate to rely on the results of the consumer study to represent consumption of regular and low-density salts.

2. One comment objected to the short-term (3 weeks) nature of the consumer

[1] The agency filed these materials in Docket 93P–0448, where they are identified as ''REF 1.'' As discussed further in section II.D. of this document, Exhibit E was removed from the original submission.

[2] In this document, the agency is citing relevant material to Serving Sizes; Reference Amount for Salt and Salt Substitutes, Seasoning Salts (e.g., Garlic Salt) that originally appeared in Ref. 2 of the proposed rule on salt products that appeared in the **Federal Register** of July 21, 1995 (60 FR 37616 at 37620). (See Docket No. 93P–0448.) For the convenience of the reader the materials are contained in ''Ref. 1'' of this document.

study, suggesting that it is likely that some consumers newly exposed to a low-density salt product would initially use less (by habit) and, eventually, could adjust the amount used to attain the desired salt flavor. The comment suggested that the adjustment period may not occur quickly and could be sufficient to distort the results of a 3-week study.

In an agency review of the petition, FDA considered concerns about the length of the study (a 6-week study period consisting of two consecutive 3-week periods, with each household receiving low-density salt during one of the two 3-week periods) (Ref. 1). FDA considered the possibility that a 3-week period might not be sufficient to estimate long term change in salt consumption when using a low-density salt product, and that salt consumption might change over a longer time period.

The agency noted in the review that the test product ratings revealed that the participants in the study did not report a sense of deprivation when using the low-density salt that would cause them to increase the volume of salt they consumed (Ref. 1). Consumption of both regular and low-density salts increased substantially over the course of the study (Ref. 1). The increases in consumption of the two types of salt were not significantly different.

The comment did not take issue with any of these findings of the study. The comment merely made general allegations about the length of the study and its ability to make valid findings.

FDA finds no merit to these general allegations given the findings of the study. Both the absence of a sense of deprivation in those using the low-density salt and the fact that the increase in consumption of low-density salt was consistent with the increase in consumption of regular salt suggest that the level of consumption of this product is likely to persist. Therefore, FDA can find nothing in this study to support the view that its results were not representative of long-term use of low-density salt.

3. One comment stated that the petitioner sponsored two studies and combined the data to determine the amount of low-density salt used. The comment asserted that, by combining the data from two studies, the consumption figures for each individual study have been irretrievably blended, and the amounts of low-density salt used in each of the two separate studies are not available. The comment stated that FDA should be concerned about this unconventional handling of data because reporting combined data suggests that direct consumption comparisons did not support the conclusions desired by the study's sponsor.

FDA does not agree that the petitioner submitted data from two studies, or that the data from separate studies were incorrectly combined. The agency notes that in 1982, the petitioner conducted one study of 320 households of salt users, using a multi-level design. The comment misinterpreted the two levels of the research design to be two separate studies. On one level of the design, data from 208 households in the sample were used to compare consumption of low-density salt that was labeled as regular salt to consumption of regular salt labeled as such. On another level, data from 112 of the households in the sample were used to compare consumption of low-density salt that was labeled as reduced-sodium salt to consumption of low-density salt that was labeled as regular salt. Thus, the study provided data describing consumption of three forms of salt: (1) Low-density salt labeled as reduced-sodium salt; (2) low-density salt labeled as regular salt; and (3) regular salt labeled as such.

Based on the study results, FDA has determined that the available data and information are adequate to verify that all data that describe consumption of low-density salt are similar and are considerably lower on a weight basis than those that describe consumption of regular salt. The data show that, for 320 households, the average amounts consumed per household over the 3-week period of the survey were as follows: (1) 170.51 g for low-density salt labeled as reduced-sodium salt; (2) 168.8 g for low-density salt labeled as regular salt; and (3) 285.75 g for regular salt labeled as such. The petitioner stated, and FDA verified, that participants used significantly less (41 percent) low-density salt than regular salt.

Thus, FDA concludes that there was a single study that provided adequate data to determine comparative consumption of low-density salt and regular salt, and that the procedures used in analysis of the data were valid.

B. Weight-Based Versus Volume-Based Reference Amount for Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt)

4. One comment objected to using the findings of the consumer study as the basis for changing from a weight-based to a volume-based reference amount. The comment stated that conclusions drawn from the data submitted in the petition do not demonstrate that salt consumption is more uniform when expressed in terms of volume than in terms of weight. The comment also objected to FDA's policy of establishing volume-based reference amounts whenever a 25-percent density variance is established by the manufacturer of a single product. The comment contended that this policy is an invitation to any food manufacturer to extend a product with 25 percent or more air and thereby to become eligible for special regulatory treatment.

Another comment supported a volume-based reference amount for salt, noting that some seasoning salts that are lighter in density than regular salt must declare the serving size as ''1/2 tsp.'' The comment stated that the proposed change to ''1/4 tsp'' would ''make seasoning salt usage more consistent overall regardless of the density of the salt or salt blend,'' would standardize information for spices and seasonings, and would be consistent with the current reference amount for spices and herbs (which is 1/4 tsp or 0.5 g if not measurable by tsp). The comment did not provide data to support the density differences among various seasoning salts.

The 1990 amendments require that nutrition information be based on a serving size that reflects the amount of food customarily consumed, expressed in a common household measure appropriate to the food. As stated in the final rule on serving sizes (Comment 20, 58 FR 2229 at 2238), FDA used weight-based reference amounts except in those instances in which it was demonstrably inappropriate to do so. The agency outlined the circumstances in which a weight-based reference amount would not adequately reflect the amount of food customarily consumed per eating occasion. FDA provided for volume-based reference amounts in cases in which: (1) The product can easily be measured by volume; (2) the density of foods within the product category varies widely; and (3) the amount customarily consumed is more uniform when expressed as a volume than as a weight. For products meeting these criteria, volume-based reference amounts ensure that serving sizes will more accurately reflect the amounts customarily consumed in accordance with the requirements of the statute.

FDA has applied this approach to all products that meet the three criteria listed previously (e.g., to mixed dishes measurable with a cup (Comment 20, 58 FR 2229 at 2238), to peanut butter (Comment 108, 58 FR 2229 at 2263), and to waffles (Comment 138, 58 FR 2229 at 2263)). This policy provides for serving sizes that accurately reflect consumption, the regulatory standard. It

does not represent special regulatory treatment of aerated food products as one comment asserted.

As stated in the proposed rule on salt products (60 FR 37616 at 37618) and acknowledged in the comments, salt products can be measured by volume. Furthermore, the density difference between regular salt and low-density salt is significant (33 percent) and demonstrates that the densities of products within the category vary widely.

In determining whether people consume similar volumes, rather than similar weights, of regular and low-density salt, FDA first considered the consumer study data submitted. FDA reviewed the mean and standard error for the consumption of regular salt labeled as such, low-density salt labeled as regular salt, and low-density salt labeled as reduced-sodium salt (Ref. 1). The agency noted that, on a per household basis, consumption of the low-density salt product was 41 percent lower by weight than consumption of the regular salt product. Because low-density salt is 33 percent lower in density than regular salt, FDA calculated that consumption of the low-density salt product was 11 percent lower by volume than consumption of the regular salt product (Ref. 2). Thus, because the percent discrepancy is less on a volume basis than on a weight basis (11 percent versus 41 percent), the study data support that salt consumption is more consistent when expressed on a volume rather than on a weight basis.

Based on the standard that FDA established in 1993 on whether to use a weight-based or a volume-based reference amount and on the consumer study data that were not available to the agency in 1993, FDA concludes that a volume-based reference amount is appropriate for salt, salt substitutes, and seasoning salts because, in addition to the fact that salt products can be measured by volume and vary widely in density, such a reference amount more accurately reflects consumption of salt and salt products and provides greater consistency in the labeling of all salts, salt substitutes, seasoning salts, spices, and herbs.

5. One comment stated that, although most recipes and cookbooks list specific volume measurements for salt, other recipes and cooking instructions state that the user should ''salt to taste'' or ''correct the seasoning.'' The comment included several articles and studies supporting FDA's initial position that a weight-based reference amount is appropriate because many consumers salt ''to taste.'' These studies indicated that: (1) Many shoppers (56 percent) modify recipes, and more than half cook without recipes at times; (2) table salt practices vary with some people adding salt before tasting (by habit) and some adding salt after tasting (to taste); (3) when people were restricted from using table salt, some compensated by increasing the salt added during cooking; and (4) when individuals were provided meals containing little or no salt, the table salt usage increased.

The comment also objected to statements made by the petitioner comparing solubility and taste of regular salt and low-density salt. The comment noted that the petitioner submitted no sensory data with the petition. The comment included study data from a taste panel that showed that four out of five respondents reported that biscuits and scrambled eggs made with regular salt tasted saltier than biscuits and scrambled eggs made with the same volume of low-density salt.

The comment concluded that nothing was presented in the petition to alter the logic of FDA's initial determination that people use ingredients such as salt or sugar ''to attain the level of sweetness or saltiness they desire'' (58 FR 2229 at 2260). The comment concluded that the reference amount for salt products should be based on weight to maintain the same level of saltiness.

FDA has reviewed the studies, articles, and cookbook information cited in the comments. It appears that there is considerable variability in how consumers use salt. The information supports that some consumers do salt or cook ''to taste'' (Refs. 3 through 5). People who salt to taste (e.g., tasting soup during preparation) are likely to use similar weights of low-density salt and regular salt. A weight-based reference amount would accurately reflect this type of use.

However, the same information supports that other consumers salt ''by habit'' (e.g., two shakes of a salt shaker) or cook according to recipe directions (e.g., by volume as specified in a recipe) (Refs. 3 through 5). These people would be likely to use similar volumes of low-density salt and regular salt because measurements of salt in recipes are specified by volume, and because the amount of salt delivered by salt shakers (i.e., the number of granules) is strongly influenced by the hole size of the salt shaker (Ref. 5). A volume-based reference amount would accurately reflect these types of uses.

FDA also reviewed the taste panel study data that were submitted in the comment comparing the taste of biscuits and eggs made with regular salt to that of biscuits and eggs made with the same volume of low-density salt. These data were ambiguous. Findings, which were included in the comment, showed that while some participants rated the biscuits and eggs made with regular salt as more salty, many reported no difference in taste, and some rated the products made with low-density salt as having a more desired, ''moderate'' salty taste.

Based on the studies and articles cited previously, when consumers at home use recipes similar to those used for the test panel, it is likely that some people will alter the recipes to produce the level of ''saltiness'' desired, which would support a weight-based reference amount. However, others will be likely to prepare the recipes as directed and thus will consume the same number of biscuits regardless of which salt is used in their preparation, which would support a volume-based reference amount.

FDA considered sensory (e.g., taste) issues in terms of their impact on consumption, the statutory standard. FDA agrees that sensory attributes (e.g., taste) may affect the amounts of regular and low-density salt used. However, the articles and studies submitted with the comments and the study data from the taste panel are ambiguous and can be interpreted to support salt use either by weight or by volume. Thus, FDA concludes that the sensory data are inconclusive in demonstrating whether similar weights or similar volumes of regular and low-density salt are customarily consumed.

C. Descriptive Labeling to Differentiate Salt and Low-Density Salt

In the proposed rule on salt products (60 FR 37616 at 37619), FDA requested comments on whether low-density salt products should be required to clearly disclose that they contain more air than conventional salt products. The agency noted that § 101.12(e), which applies to discrete products like waffles, requires that the aerated version bear a descriptive term indicating that air has been incorporated (e.g., whipped, aerated). FDA stated that some product categories that have volumetric reference amounts contain products with common or usual names that clearly indicate that air has been incorporated into the product (e.g., whipped peanut butter, whipped dessert topping). Some products in other product categories with volumetric reference amounts do not bear such descriptive terms (e.g., pudding, ice cream).

The agency stated that because regular salt and low-density salt have similar appearances, terms such as ''whipped

salt'' or ''aerated salt'' could be confusing to consumers. Therefore, FDA requested comments on what kind of descriptive terms would be clear and nonmisleading for consumers.

6. One comment stated that some kind of differential labeling (e.g., ''aerated salt'' or ''fluffed salt'') should be required to prevent misbranding and to allow consumers to make an informed purchasing decision.

FDA agrees that descriptive labeling is needed on low-density salt to ensure that consumers understand how this product differs from regular crystalline salt and are fully informed about important product characteristics. Section 101.3 (21 CFR 101.3) establishes requirements for the statement of identity of a food. Section 101.3(c) requires that when a food is marketed in various optional forms, the particular form shall be considered to be a necessary part of the statement of identity. Terms such as ''low-density salt'' or ''flaked salt crystals'' would meet these requirements because they describe the characteristic that distinguishes low-density salt from regular crystalline salt. This information must appear as part of the statement of identity on the principal display panel under § 101.3.

As stated in the second paragraph of section II.C of this document, FDA expressed concern in its proposed rule on salt products, that, because low-density salt looks similar to regular salt, some terms (e.g., ''aerated'' or ''whipped'') might be confusing to consumers. However, if manufacturers conduct consumer studies that demonstrate that terms such as ''aerated,'' ''fluffed,'' or ''whipped'' are understood by consumers as distinguishing low-density salt from regular salt, these additional terms or descriptions could also be used. FDA concludes that the statement of identity for a low-density salt product must not be false or misleading and must include a description of the form of the salt. If a product does not bear such a statement of identity, it would be subject to regulatory action under section 403(i)(1) of the act.

D. Marketing Strategy Information

7. One comment stated that some of the relevant data were not included as part of the public record. The comment noted that a volume-based reference amount accommodates a misleading marketing strategy for low-density salt. Consequently, the comment contended that the materials contained in Exhibit E of the supplemental materials[1], which were identified as pertaining to marketing strategies and which were removed from the supplemental materials before filing the materials in the docket, need to be made publicly available to ensure informed comment before any final action is taken.

All relevant data and information were included as part of the public record. The agency does not agree that materials pertaining to marketing strategies (Exhibit E in the supplemental materials) needed to be made publicly available to ensure informed comment. The material contained in Exhibit E does not contain any information relevant to a decision on the determination of a reference amount and serving size for salt products, and the agency did not use any of the material contained in Exhibit E during its deliberations. Marketing strategies fall within the definition of confidential commercial information (e.g., valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged). Thus, these materials are not available for public disclosure under 21 CFR 20.61.

III. The Final Regulation

FDA determined in 1993 that volume-based reference amounts are appropriate when: (1) Products are bulk products that can be measured by volume (final rule for serving sizes, comment 20, 58 FR 2229 at 2238; and comment 108, 58 FR 2229 at 2263); (2) there are significant differences in densities among the products within a product category, such that a range of densities are represented within the product category (see discussions on aerated products (§ 101.12(e)) and peanut butter (final rule for serving sizes, 58 FR 2229 at 2263)); and (3) the amount customarily consumed is more uniform when expressed in terms of volume; that is, there is some indication or likelihood that similar volumes, rather than similar weights, of both low- and high-density products within the same product category are customarily consumed (proposed and final rules for serving sizes, 56 FR 60394 at 60406, November 27, 1991; and 58 FR 2229 at 2238).

Although the sensory data, discussed in section II.B of this document, indicate that there is variability in how salt products are used, the evidence from the consumer study of consumption patterns for regular and low-density salt, outlined and discussed in sections II.A and B of this document, supports that people consume more similar volumes than weights of salt products. Because of this fact and the facts that the products within the category can be measured volumetrically, and the density differences among products within the same product category are significant, FDA concludes that it is appropriate for the reference amount for salt and salt products to be expressed as a volume rather than as a weight. Therefore, the agency is changing the reference amount for salt and salt products in § 101.12(b), Table 2, from ''1 g'' to ''1/4 tsp.''

IV. Effective Date

Compliance with this final regulation, including any required labeling changes, may begin January 2, 1998, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2000, shall fully comply.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule on salt products (60 FR 37616 at 37619). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Analysis under Executive Order 12866

FDA has examined the economic implications of the final 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 final rule is not a significant rule as defined by Executive Order 12866.

FDA received one comment which objected to the agency's tentative finding that there is no cost to industry. The comment explained that some labels would need to be modified and requested a 1 year phase in period to allow industry to exhaust current label inventories.

FDA agrees that some labels will need to be modified at a small cost to industry—approximately $600 per label on average. Based on information submitted by the comment, there are

167 labels that will need to be relabeled as a result of this rule (Ref. 6). Although FDA recognizes that there may be more items requiring relabeling than those with which the agency is familiar, the number is not likely to be large. If there are approximately 200 labels affected by this rule, then the costs will be $120,000.

In the section IV of this document, FDA stated that this final rule has a compliance date in accordance with the uniform compliance date for food labeling requirements which is not sooner than 1 year following publication of this rule.

VII. Small Entity Analysis

FDA has examined the economic implications of the final 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.

FDA is not aware that any of the items that will require relabeling are produced by small entities, defined as fewer than 500 employees. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

VIII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject review by OMB under the Paperwork Reduction Act of 1995 (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 and recordkeeping 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: Serving Sizes; Reference Amount for Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt).

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) (21 CFR 101.9(d)(3)) that require the nutrition facts panel on the label of a food product disclose information on serving size and on servings per container. FDA has also issued regulations in § 101.9(b) that provide that the serving size shall be determined based upon the ''Reference Amounts Customarily Consumed Per Eating Occasion'' that are prescribed in § 101.12(b).

This final rule revises the value for the reference amount customarily consumed per eating occasion for the food category ''Salt, salt substitutes, seasoning salts (e.g., garlic).'' This value is used by food producers to determine the serving sizes and number of servings to be listed on packages of salt, salt substitutes, and seasoning salts (e.g., garlic). As a result, manufacturers and other producers of certain of these products will be required to change the serving sizes and number of servings per container that they disclose in the nutrition facts panel for their products.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

21 CFR Section	No. of Respondents	Total No. of Responses	Hours per Response	Total Hours	Total Operating Costs
101.12(b)	5	200	1	200	$120,000

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

FDA believes that the burden associated with the disclosure on the label of serving size and number of servings that would be required by this final rule will be a one-time burden created by the need for firms to have to change the statement of serving size and number of servings on the labels for their products. Because firms already list the serving size for salt, salt substitutes, and seasoning salts (e.g., garlic) in terms of ''1/4 teaspoons,'' FDA believes that the only firms that will have to revise their labels as a result of the regulation codified in this document are those that market low-density salt products. As noted in Table 1 of this document, FDA estimates that there are less than five firms producing salt, salt substitutes, and seasoning salts (e.g., garlic) that will need to change the labels for their products. FDA estimates that these firms will require an average of 1 hour per product to comply with the requirements of this final rule. Further, as noted in Table 1 of this document, the final rule would result in a one-time operating cost of $120,000.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection requirements of this final rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 2, 1998, to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Brenda M. Derby, CFSAN, FDA, to Ellen M. Anderson, CFSAN, FDA, June 20, 1994.

2. Bender, Mary M., and Ellen M. Anderson, memorandum to file, August 28, 1997.

3. Mittelmark, Maurice B., and Barbara Sternberg, ''Assessment of Salt Used at the Table: Comparison of Observed and Reported Behavior,'' *American Journal of Public Health*, 75:1215–1216, 1985.

4. Gilbert, Linda, contributing ed., ''Leisure Cooking Still Popular,'' *Food R & D*, February 1985.

5. Greenfield, H., J. Maples, and R. B. H. Wills, ''Salting of Food—A Function of Hole Size and Location of Shakers,'' *Nature*, 301:331, 1983.

6. Letter from Marlene L. McKone, McCormick & Company, Inc., to Ellen M. Anderson, CFSAN, FDA, September 26, 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, 21 CFR part 101 is 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), in Table 2, under the ''Product category'' column, under the ''Miscellaneous Category'' by revising the entry for ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' 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]
* * *	* *	* *
Miscellaneous category:		
* * *	* *	* *
Salt, salt substitutes, seasoning salts (e.g., garlic salt).	1/4 tsp	1/4 tsp (____ g); ____ piece(s) (____ g) for discrete pieces (e.g., individually packaged 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: November 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–31462 Filed 12–1–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97P–0206]

Food Labeling: Health Claims; Dietary Sugar Alcohols and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to amend the regulation that authorizes a health claim on sugar alcohols and dental caries to include the sugar alcohol erythritol among the substances that may be the subject of the claim. Based on its review of evidence submitted with a comment on the proposal, and the evidence described in the proposal, the agency has concluded that there is significant scientific agreement that erythritol does not promote dental caries. Therefore, FDA has decided to amend the sugar alcohol and dental caries health claim to include erythritol. FDA is announcing this action in response to a petition filed by the Cerestar Holding B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co. (the petitioners).

EFFECTIVE DATE: December 2, 1997.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, 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

In the **Federal Register** of July 9, 1997 (62 FR 36749), the agency proposed to amend the regulation that authorizes a health claim on sugar alcohols and dental caries (§ 101.80 (21 CFR 101.80)) to include the sugar alcohol erythritol among the substances that may be the subject of the claim. FDA issued the proposed rule in response to a petition filed under section 403(r)(3)(B)(i) and (r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i) and (r)(4))). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations authorizing health claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence