



## TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

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May 19, 2005

U.S. Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket Numbers 2004N-0456 and 2004N-0463

Dear Sir or Madam:

As the Commissioners of the Texas Department of Agriculture and the Texas Department of State Health Services, we are pleased to provide these comments regarding the recent Advance Notice of Proposed Rulemaking (ANPRM) on the labeling of caloric content of foods and serving sizes for foods that may be consumed at one eating occasion. We consider the current trend toward obesity in the U.S. to be of epidemic proportions, and it is our hope that modification of current food labeling requirements and single-portion containers will lead to improvements in the overall health of our citizens. We trust that these comments will assist you in this important endeavor.

Embodied in the two ANPRMs recently published by the U.S. Food and Drug Administration (FDA) are numerous questions regarding the impact any revisions to the Nutrition Facts Panel (NFP), the prominence of certain label statements, and the Reference Amounts Customarily Consumed (RACCs) for specific food categories, would have on the consumption of certain foods by the public, and the impact on container sizes as they might be revised by industry. Although we have not engaged in consumer research along these lines, we believe the following comments are justified based on the previous experiences of our regulatory programs and our desire for a healthier, more balanced diet for our citizens.

First, we believe that more prominence should be given to "calories per serving," but this should be combined with a requirement to list total calories per container. For example, take a box of sugar coated cereal that contains eight (8) servings based upon the current FDA serving size for such a product. Since most consumers do not weigh product before preparing or consuming a food, the number of actual servings they may consume from the box may be more or less than eight, depending on the size of their cereal bowl. Listing total calories (e.g. "This box contains a total of 2,560 calories [320 calories x 8 servings]) will provide more direct information to consumers as to just how many calories they are actually consuming, at least over time. If the box lasts only five days, the consumer will have the information on their total caloric intake from the box of cereal.

We also recommend increasing the type size and font for statements on caloric content. The type size should be increased to be two points larger than other information on the NFP (i.e. minimum of 10 point type) and in a font that produces wider letters. We also believe that listing the total calories in the container should suffice, since few consumers will consume the entire box in one day; or put the total calories per container in the context of a single day's recommended caloric consumption.

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Calories from Fat. Given today's dietary recommendations, it appears that listing total calories plus calories from fat may be either confusing or at least distracts from the total amount consumed. It appears that FDA's own focus groups pointed this out as well. The disadvantage to eliminating "calories from fat" would appear to be a loss of emphasis on the amount of fat being consumed per serving. Perhaps it is more important, though, to concentrate on the *type of fat* being consumed rather than on total calories from fat. Even so, BOTH could be displayed if color-coded. In fact, two columns in the NFP would be acceptable if color-coded (one column for total consumed per package, another per serving for packages that indeed contain more than a single serving [single eating occasion]).

In response to your questions assuming that calorie content labeling affects consumer decisions on whether to eat a food and how much to eat, we repeat our comments on serving size. Since portion size for a consumer is hard to judge unless the food is in a form that can be cut or otherwise easily divided by the recommended serving size, the number of calories per serving is a very relative figure. On the other hand, if/when TOTAL calories per container are listed, this combined with calories per serving would have more meaning. If FDA determines to keep the Nutrition Facts Panel almost intact, then prominence of the calories per serving should aid consumers only if FDA also provides for the mandatory labeling of total calories. The two should be complementary.

Labeling caloric content per package and with greater prominence would most certainly stimulate more competition among manufacturers. We believe companies that have increased the sizes of single serving containers over the years (example: soft drinks have gone from 6 ounces, to 10, 12, 16, and now 20 ounce single serving sizes in the last 50 years) will either return to smaller size containers, emphasize their smaller size products (marketing and advertising), or in some instances re-formulate to reduce the caloric content. At the same time, if total calorie content is required to be disclosed separately on the label, (again for competitive reasons) we may see multiple serving snack foods in smaller packages, such as cookies and chips, in order to lower the overall calorie content of the package.

Under the Nutrition Labeling and Education Act (NLEA), companies initially reduced the amount of fat in various products as a marketing tool. However, often there was not a corresponding reduction in calories, which was a disservice to consumers who thought they were eating healthier. Therefore, revisions to the system are needed. Since the RACCs have remained unchanged, companies have increased the sizes of single service containers. Consequently, certain aspects of the Nutrition Facts Panel (NFP) have become misleading to consumers of these larger packages. We recommend surveying the public to determine the sizes of containers for specific types of foods that they consider to be "single servings," combined with an FDA review of the marketing materials utilized by companies.

Further, if the manufacturer exceeds the amounts for such serving sizes as determined by consumer surveys by less than fifty percent, the package should still be considered a "single serving." This would discourage manufacturers from further increasing the size in order to escape any new "single serving" requirements.

We believe the competition will once again be the driving force that is the incentive for manufacturers to reduce the sizes of single serving packages, especially for foods that contain significant amounts of certain nutrients (fat), including calories. Consequently, there should be no reason to re-define "serving" or "serving size" – only what may *constitute* these in terms of the specific foods or specific packaging sizes. On the other hand, there is a strong need to be careful before revising the definition of "customarily consumed" (especially upwards!), or FDA will defeat the purpose of any revisions to the regulations, such as lowering consumer intake of calories, smaller portion sizes, and the like.

FDA must also be careful not to further confuse consumers with respect to the difference between the Percent Daily Value (DV) and the amount of nutrients that would be consumed in one sitting when consuming a single serving container that significantly exceeds the RACC. It may be that FDA will determine that to avoid such confusion, nutrition information for an entire single serving package should be declared in total rather than as a percentage of the DV. The DV could still be listed on the NFP and yet no longer list the nutrition information as a percentage. We also believe that listing the two side-by-side in separate columns would further confuse consumers.

With respect to the use of label claims, we would urge FDA to not permit the use of such claims *unless* smaller containers for single servings result in a qualified claim. If the claim becomes justified according to current regulations based upon the amount of product in the single serving container, this could be an incentive for industry to indeed reduce the sizes of these containers. By reducing the portion sizes for these containers, both industry and consumers win. We also agree with FDA's example that the size of the compared servings or package should be a part of the claim so as not to mislead the public. We do not believe that if the portions were reduced in a reasonable manner that this would lead to consumption of multiple packages in one sitting, which if it occurred, would defeat the entire purpose of emphasizing total caloric content and the reduction in portion sizes. The ability to make specific (approved) claims for their products is probably the greatest incentive of all for manufacturers to reduce the sizes of their single-serving containers.

Again, we wish to thank FDA for providing the opportunity to comment on this very important subject. If further information or clarification is required, please contact Mr. Dan Sowards, Food and Drug Safety Officer, Texas Department of State Health Services, at 512-719-0243 or via email at [dan.sowards@dshs.state.tx.us](mailto:dan.sowards@dshs.state.tx.us).

Sincerely,



Eduardo J. Sanchez, M.D., M.P.H.  
Commissioner  
Texas Department of State Health Services



Susan Combs  
Commissioner  
Texas Department of Agriculture