

June 13, 2005

Via email to: fdadockets@oc.fda.gov
Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Subject: Docket No. 2004N-0463; RIN 0910-AF22

With reference to the above docket, McNeil Nutritionals, LLC, submits the following comments in response to the questions posed in the Food and Drug Administration (FDA) advance notice of proposed rulemaking (ANPR) on whether to amend the nutritional labeling regulations to give more prominence to calories on food labels.

A. Questions Concerning Prominence of Calorie Information on Food Labels

- *Would consumer awareness of the caloric content of packaged foods be increased by amending nutrition labeling regulations to give more prominence to the declaration of calories per serving? Why or why not?*

McNeil Nutritionals, LLC, believes that giving more prominence to the declaration of “Calories Per Serving” would increase consumer awareness of the calorie content of packaged food, when coupled with a %DV disclosure for total calories. In the absence of a %DV disclosure, more prominence to “Calories Per Serving” would otherwise be helpful. However, making the connection to show the impact of consuming a particular food on total daily calorie intake would make the information more usable. The ability of consumers to understand this “connection” when making choices is most important. Accordingly, we also strongly believe that any effort to give greater prominence to “Calories Per Serving” must be accompanied by an educational outreach effort to aid consumers in understanding this connection.

Ideally, appropriate on label text and/or graphics can be developed to reinforce the connection, since the ability to understand even simple percentage declarations may be lacking in many consumers who are or who may be at risk for obesity. Additionally, more meaningful serving size information, i.e., based on quantities “actually” eaten, would aid consumers in understanding the impact of the food choices they make.

- *How would a more prominent listing of calorie information change the way consumers use the NFP in deciding what to eat?*

Giving prominence to any one piece of information will cause it to stand out and, hopefully, give consumers pause to evaluate its importance. However, just giving prominence to calories, without providing tools to assist consumers in either calculating or estimating total daily caloric intake is a half-measure at best. The Obesity Working Group’s research bore this out. The caloric value of a serving of food is a “snapshot”, whereas each day’s total calorie intake is a short “movie”. Thus, while adding prominence to calorie information is an important first step, educating consumers so that they know how to use the information to make choices throughout the day is the key.

Another significant issue that the ANPR fails to address concerns the contribution to daily caloric intake of restaurant foods and home-prepared meals. The obesity epidemic is a complex issue. Thus, while giving more prominence to “Calories Per

Serving” and adding a “%DV for calories” on packaged foods are positive steps, how do consumers incorporate information about the caloric intake of foods consumed either away from home or from meals eaten at home? A meal usually consists of several ingredients, each with its own caloric value. So, while it may be fairly straightforward to assess caloric intake from a discreet, pre-packaged meal (can of soup) or meal replacement product, this becomes problematic when preparing and eating a meal made from several packaged and/or fresh ingredients, especially where there may be little or no portion control reference.

Thus, while we agree that more prominence to calories coupled with a %DV for calories are good ideas, it represents only a starting point for helping consumers understand energy balance issues.

- *What methods could be considered for increasing prominence? For example, should the font size be increased for the listing of “Calories” from the current requirement of 8-point type, and/or should extra bold type or a different style of type be used?*

Increasing the font size and bolding it are the simplest means to give prominence to calories on a food product label. Again, while we believe that giving such prominence could increase notice of the calorie information, the novelty of the increased prominence is likely to fade with time, unless consumers are also provided a simple means to better understand the caloric impact of a serving of food on total daily caloric intake.

- *Would providing for a %DV disclosure for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000-calorie diet? Why or why not?*

As noted above, we believe that providing a %DV for calories in the Nutrition Fact Panel is a necessary corollary to making the “Calories Per Serving” declaration more prominent. At the very least, the %DV provides a modicum of additional information with which those who are capable can make a connection between the caloric intake from an individual serving of a food and its impact on total daily calorie intake. However, we question the ability of a significant portion of consumers to make effective use of a %DV for calories in managing caloric intake. We recommend that FDA assess whether consumers would be better able to understand energy balance issues merely through increased prominence and a %DV for calories.

Questions concerning Calories from Fat

- *What are the advantages or disadvantages of eliminating the listing for “Calories from fat” from the nutrition label?*

We see no downside to eliminating the listing for “Calories from Fat”. In removing this declaration, we also suggest moving the “Calorie” declaration below the “bold line”, to a position just above the “Total Fat” declaration. It may also be useful to provide a more prominent and meaningful link between the “Calories per gram of fat, protein, and carbohydrate”, shown at the bottom of the NFP, with the gram amounts per serving of fat, protein, and carbohydrate. Doing so might help consumers better understand the calorie contribution of these major food components in a serving of the food.

- *What data would be needed to determine whether the listing of “Calories from fat” is or is not necessary to assist consumers in maintaining healthy dietary practices?*

Obesity levels have gotten markedly worse over the past 10 years, during which time the NLEA has required a “Calories for Fat” declaration on food product labels. In view of this growing obesity epidemic, isn’t it obvious that a different approach is needed? Simply put, why waste time and money collecting information on what we already know. The current state of the nation’s weight problem is justification enough that the “Calories from Fat” declaration has made little if any difference.

- *What data would be needed to determine whether the listing of “Calories from fat” is or is not necessary to assist consumers in maintaining healthy dietary practices?*

We believe that the current obesity problem in the U.S. clearly indicates that the “Calories from Fat” declaration, when viewed either alone or in tandem with the current NFP “Calorie” declaration, has had little impact on consumers. Rather than spend the time and money to assess the continued usefulness of a “Calories from Fat” declaration, it would be better to use the resources to develop a tool to help consumers better understand a “%DV Calorie” declaration.

However, if it is absolutely necessary to develop such data before making a decision on the continued use of the declaration, one could: (a) identify a group of consumers who claim to use the “Calories from Fat” declaration to make food consumption choices; and, (b) determine if/how their body weight either changes or has changed during the time they claimed to have used the declaration. Presumably, if they have been using the information effectively to modify eating behavior, it should have a positive outcome on bodyweight.

C. Questions About Use of Calorie Information on Food Labels

- *Is calorie content used to determine how much of a given food to eat, or to determine which foods, out of a range of similar products, to eat? Why or why not?*

Based on the magnitude of the obesity epidemic, we would argue that the evidence suggests that, if the NFP is being used, it does not appear to be having an impact.

- *If calorie labeling affects decisions on whether to eat a food and on how much to eat, how would the effects of the following requirements differ: A requirement to display the number of calories per serving on the PDP, or*

In our view, the calorie information should appear with the other nutrition information in the NFP and include a tool that is more useful to consumers than the current format. A simple calorie declaration on the product PDP, without additional explanation, could (as shown by the OWG data) be misleading and, potentially, negatively affect purchase intent of otherwise healthful and beneficial foods.

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

As noted above, we believe that increasing the prominence of the “Calories per Serving” in the NFP is the right first step to take in any effort to improve the NFP.

D. Questions About Reformulation of Foods Or Redesign of Packaging

- *Would the display of caloric content per package on PDPs encourage more competition based on the caloric content of packages and, if so, how?*

We do not believe that displaying the caloric content of an entire package on the PDP is of any value, except perhaps for unit of use products. Rather, we believe that a

mandate to list total calories could negatively affect purchase intent of foods that might otherwise be very useful in controlling caloric intake or consumed for some other benefit (health claim).

We also believe that placing total caloric content of a package on the PDP could cause confusion. For example, some artificial sweeteners make “zero calorie” or “no calorie” claims on the products’ PDP, based on a per serving basis (i.e., the sweetness equivalent of one teaspoon of sugar.) These products do, however, provide minimal calories. Thus, to require this product to list total calories on its PDP, when it is labeled as a “No Calorie” Sweetener could be confusing at the very least.

- *If the calorie content per serving were required to be more prominently displayed on the NFP, would it encourage more competition based on the calorie content of the food?*

Certainly, a more prominent display of calorie content on the NFP might encourage competition through the reformulation of products, much in the same way that displaying “Calories from Fat” once did. But, product reformulation and repackaging do not necessarily equate with better products. Indeed, following the publication of the NLEA regulations, some foods that were reformulated to decrease their fat content wound up having as many or more calories per serving by the addition of carbohydrate.

However, reformulation or re-packaging is not the point. Clear and simple, the objective is to get the American consumer to eat less and exercise more and, in doing so, to help them understand energy balance – that calories consumed should be balanced with calories expended.

Research has shown that even modest decreases in total daily caloric intake can have a meaningful impact on body weight. Thus, in our view, it is more important to provide consumers with the knowledge and tools to make more informed choices about what they are eating now, rather than to depend on product reformulation or re-packaging to produce the desired effect.

- *Would the result be products reformulated to have fewer calories per serving, for example greater use of no calorie sweeteners?*

Clearly, the current availability of a variety of no calorie sweeteners, used singly or in combination makes it easier for food formulators to develop lower calorie alternatives to traditional foods and beverages. Additionally, unlike the pre-NLEA era, when the use of these sweeteners required the finished product to be at least 33% reduced in calories, food formulators can now use no calorie sweeteners for more modest calorie reductions. Additionally, the use of a no calorie sweetener no longer obligates the manufacture to use what many view as pejorative terms such as “low calorie”, “reduced calorie”, even if the products meet the definition for these nutrient content claims.

One action that FDA could take to stimulate the development of lower calorie foods would be to amend the standards of identity to permit safe and suitable no calorie (non-nutritive) sweeteners in these foods, without the need to label these products with modified standardized names, e.g., “Reduced Calorie Chocolate Milk”, as required by 21 CFR §130.10. We believe that the listing of the non-nutritive sweetener in the product ingredient statement is enough.

Indeed, given the quantities of nutritive sweeteners in many standardized products, safe and suitable non-nutritive sweeteners should be accorded a level playing field so

that their presence does not have to be called out on the PDP by the use of a modified standardized name. Indeed, one could argue that given the obesity issue, the reverse should be true, with the presence of nutritive sweeteners called out on the product label.

- *Would it result in any repackaging of products offered? How would this option change the kinds of products offered?*

We believe that more prominence to the “Calorie Per Serving” declaration on the NFP, along with a %DV declaration, and especially if coupled with more realistic serving size information could be a stimulus for repackaging products into smaller serving sizes. Some beverage manufacturers have already begun to do this. If smaller packages are an outcome of revised calorie labeling requirements, we hope that food manufacturers price them so that they are not more expensive than larger sizes. To do so would encourage consumers to continue to buy and consume larger sizes. Consumers are not ignorant about price comparisons. To charge more for a product because it is packaged in smaller units would discourage purchase intent.

- *If the calorie content per package were required to be prominently displayed on the PDP, would it encourage more competition based on the calorie content of the food? Would the result be repackaging of products into smaller units, for example repackaging cookies into 100-calorie packages?*

We do not believe that prominently displaying the calorie content on the PDP of a food product label is the way to address this issue. Moreover, while simply re-packaging products might have some impact, it is not the answer. There would be nothing to stop consumers from purchasing and consuming more than one package of cookies no matter how small the units. What is important is how to better communicate the caloric impact of each food choice made during the day on total daily calorie intake.

- *Would there be any incentive to reformulate under this option? How would this option change the kinds of products offered?*

We expect that some processed food manufacturers will be stimulated to reformulate their products to provide lower calorie options. The key is how best to ensure that these lower calorie options become mainstream much the same way that some diet soft drinks have.

- *Are you aware of any research, consumer or industry-based, that can assist the agency to answer any of the previous questions?*

We are unaware of any specific research in this area.

McNeil Nutritionals, LLC, appreciates the opportunity to comment on this issue and trusts that the foregoing will be useful to FDA in formulating future activity in this area.

Sincerely,

Richard R. Reo
Director, Regulatory Affairs