

October 28, 2004

Acting Commissioner Lester Crawford, Ph.D., D.V.M.
Food and Drug Administration
5600 Fishers Lane, 14-71
Rockville, MD 20857

Re: Misbranding of Single-serving Foods

Dear Dr. Crawford:

Obesity has become an issue of national importance to Americans. The dramatic increase in product serving sizes over the last decade, particularly the advent of super-sized soft drinks and large packages of baked goods and snacks, appears to have contributed to soaring obesity rates.

Consumers may be misled by labels that provide information for fractions of packages of foods, when those packages are typically consumed as a single serving. For example, the Nutrition Facts panel on a 20-ounce beverage states that the bottle contains 2.5 100-calorie servings. However, normally the entire bottle is consumed as a single serving, providing 250 calories.

The Center for Science in the Public Interest (“CSPI”) is pleased that the Food and Drug Administration (“FDA”) has designated modernizing serving-size regulations as one useful, if small, measure for fighting obesity. We specifically urge the FDA to:

(1) Take enforcement action against manufacturers that mislabel products as containing multiple servings when they are typically consumed in one eating occasion, in violation of §403(a) of the Federal Food, Drug, and Cosmetic Act (“the Act”) 21 U.S.C §§301 et seq.;

(2) Initiate a rulemaking proceeding to revise the current regulations to reflect the dramatic changes in consumption patterns that have developed since they were issued 11 years ago (indeed, many RACCs were based on data published by USDA in 1982 and collected in the 1977-78 Nationwide Food Consumption Survey. Soft drinks and baked goods of sizes up to and including 300% of the reference amount currently consumed (“RACC”) should be defined as single-serving products. Snack foods containing up to 400% of the RACC amounts should be labeled as single-serving products if the package is typically consumed by one person at one time. Snack foods containing between 200% and 400% of the RACC that may either be consumed at one time or as multiple portions should be required to include two columns to provide nutrition information on a per-serving and per-package basis. In addition, such packages should be required to bear the statement “contains ____ servings” on the Principal Display Panel.

Products in other categories, such as candy bars, dried soups, frozen entrees, pizza crusts, and fruit cups, also come in over-sized single-serving packages. The FDA should consider taking enforcement action against some of those products, too. Several major manufacturers voluntarily are beginning to provide information about the contents of entire packages, but the nature of that information is not always consistent. FDA regulations are needed to ensure that the serving-size information will be consistent and as clear as possible to consumers.

The basis for these recommendations is summarized below and explained in depth in the accompanying Petition for rulemaking on the nutrition labeling of foods and beverages sold in oversized single-serving containers.

I. Background

Under existing regulations, manufacturers of products containing more than 200% of the RACC have the discretion to label such products as a single-serving “if the entire content of the package can reasonably be consumed at a single-eating occasion.”¹ However, the Preamble to FDA’s serving-size regulation limits that discretion in situations where the product is “obviously” intended to be consumed in one serving. The Preamble states:

regardless of the package size a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as “singles” or “the perfect size for one”) must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act (emphasis added).²

As will be explained in detail below, many soft drinks and snack foods are being sold in what are obviously single-serving containers but the containers are labeled as containing multiple servings. In addition, baked goods, such as muffins, that are sold in discrete units are also labeled as containing multiple servings. Clearly, such labeling violates Section 403(a) of the FDCA. That provision deems a product misbranded if “its labeling is false or misleading in any particular.” Large, single-serving packages that pretend to provide several servings are clearly misleading.

Instead of bringing enforcement actions, however, FDA did nothing for years, then simply encouraged “manufacturers to provide the most accurate and useful nutrition information to consumers by taking advantage of the flexibility in current regulations on serving sizes and label food packages as containing a single-serving if the entire contents of the package can reasonably be consumed at a single-eating occasion.”³ That gives manufacturers a mixed

¹ 21 C.F.R. § 101.9.

² 58 Fed. Reg. 2229, 2233 (Jan. 6, 1993).

³ CFSAN/Office of Nutritional Products, Labeling and Dietary Supplements, *Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, (Mar. 12, 2004).

message by encouraging them to do one thing, but allowing them to do another. The seriousness of the obesity epidemic confronting this country calls for a stronger response by FDA.

Although FDA has publicly stated its intent to revise the Agency's serving size regulations, the notice and comment rulemaking process is a lengthy one. While such a proceeding is pending, many consumers will be misled into consuming extra calories. Therefore, FDA should take enforcement action promptly to prevent misleading labeling of large single-serving packages. FDA has the authority to take enforcement action at this time.

A. New Evidence Overcomes FDA's Previous Objections to Imposing Single-Serving Requirements on Soft Drinks and Snacks

FDA discussed the precise question of whether to require over-sized beverages and snacks to be labeled as single-serving products during its 1991-1993 rulemaking proceeding on serving sizes. At that time, FDA rejected such an approach, stating:

FDA does not believe that it is appropriate to change the definition of a single-serving container so that certain sizes of a selected class of products can be labeled as a single serving or to set a different requirement for a selected class of products without food consumption data or a scientifically sound basis that supports such a different requirement.⁴

FDA's previous objections to requiring that super-sized products be labeled as single servings are no longer relevant because new evidence demonstrates that super-sized products are widely consumed on single-eating occasions. In addition, as discussed in greater detail in Section II, major manufacturers of over-sized products refer to the fact that they are sold in single-serving containers on the packages themselves, in advertising or on their websites. Such products "are obviously intended to be consumed in one serving" and are in violation of Section 403(a) of the Act, as acknowledged by FDA in the Preamble to the serving-size regulation.

B. Prior FDA Policy Conclusions in the 1993 Preamble Should Not Bar Enforcement Actions

Some companies might argue that FDA's 1993 explanation as to why it was not requiring single-serving size designations for over-sized soft drinks and snacks constitutes a binding advisory opinion that prevents the Agency from taking enforcement action at this time.⁵ However, FDA no longer considers advisory opinions to be binding in circumstances such as this one.

Prior to 1992, FDA's own rules prohibited the Agency from recommending "legal action against a person or product with respect to an action taken in conformity with an advisory

⁴ 58 Fed. Reg. at 2233.

⁵ 21 C.F.R. § 10.85(d).

opinion which has not been amended or revoked.”⁶ In 1992, however, FDA departed from that approach, citing a number of court cases that held “that the agency cannot be estopped from enforcing the law.”⁷ FDA proposed the following language:

An advisory opinion represents the best advice of FDA on a matter at the time of its issuance. However, an advisory opinion does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. FDA, may, in its discretion, recommend or initiate legal or administrative action against a person or product with respect to an action taken in conformity with an advisory opinion, provided that the legal or administrative action is consistent with applicable statutes and regulations.”⁸

Although the 1992 proposal has not been finalized, its Preamble, nevertheless, constitutes FDA’s latest policy on this point. Therefore, FDA should not refrain from taking enforcement action against manufacturers who misleadingly label over-sized products that are typically consumed at a single occasion. Sending warning letters to manufacturers of super-sized products that are labeled as containing multiple servings is fully appropriate under Section 403(a) of the Act. In addition, enforcement actions against products that are sold in containers obviously intended for a single serving do not represent any change in FDA’s policy since that approach was set forth in the 1993 Preamble.

Warning letters to several prominent companies, accompanied by product seizures, would send a strong signal to the entire industry that FDA treats misbranding of such packages as a serious issue. CSPI recommends that FDA initially target three categories of products that appear to be the worst offenders on the market: soft drinks, snack foods, and baked goods.

II. Soft Drinks and Other Beverages

According to one recent vending-industry report, 20-ounce bottles became the leading single-serve configuration in convenience stores several years ago, and the vending industry, which caters to the individual consumer, continues to catch up to this trend.⁹ Bottles displaced cans in vending machines for the seventh consecutive year in 2002, grabbing 44.9% of all cold-drink sales.¹⁰ Yet, 16-, 20-, and 24-oz. bottles of beverages (soft drinks, milk-based drinks, juices, and fruit drinks), which have a reference amount of 8-oz. (240 ml), are frequently labeled as containing 2, 2.5, or 3 servings per container even though the packages are marketed and consumed as single servings.

⁶ 21 C.F.R. § 10.85(e). That provision, although still technically in effect, is no longer followed.

⁷ 57 Fed. Reg. 47314, 42415 (Oct. 15, 1992).

⁸ 57 Fed. Reg. at 47317.

⁹ “2003 State of the Vending Industry Report,” *Automatic Merchandiser*, August 2003. <http://www.amonline.com/PDF/AutomSOVI2003.pdf> (accessed July 28, 2004).

¹⁰ *Id.*

In some cases, labeling or advertising indicates that products are intended to be consumed as a single serving. For example:

- Coca-Cola is sold in 24-oz. bottles that state on the label: “It’s Big! For those who thirst for more.” The label states that the product provides three 8-oz. servings.
- Pepsi advertises its Sierra Mist soft drink in a TV commercial that shows two soccer players fighting over the last 20-oz. bottle in the cooler, implying that one person would consume the whole bottle. The label indicates that the bottle provides 2.5 servings.
- Tropicana Products, Inc., tells customers on its website to “look for Tropicana Twister in 20-oz. single-serve bottles,” but it lists the calorie content for just half the bottle on the nutrition label.¹¹
- AriZona Beverages refers on its website to its 24-oz. can of iced tea as a “single serve” product while listing nutrition information for 8 ounces.¹²
- Welch Foods, Inc., declares on its website that each 16-oz. bottle of its single-serve juice line contains an individual serving while listing nutrition information for 8 ounces.¹³

Clearly, the labeling for those products is misleading.¹⁴

III. Snack Foods

Snack foods, which include chips, popcorn, pretzels, and similar foods, have a reference amount of one ounce (28 g). Nevertheless, larger packages of snack foods that are likely to be consumed as a single serving have become increasingly prevalent. Salty-snack manufacturers introduced a category of larger snack bags called Large Single-Serve (“LSS”) to the vending industry in 1994, which contributed to the “upsizing” trend in snack foods.¹⁵

Recognizing the need to improve the labeling of its snacks, Kraft Foods, Inc. plans to label packages that contain two to four servings (200% to 400% of RACC) as follows: Products typically consumed by one person at one time will be labeled as a single serving. If the product is sometimes consumed by one person, but usually by more than one person, Kraft will provide nutrition information for both the full package and per serving. Kraft will also state on the front

¹¹ See <http://www.tropicana.com/index.asp?id=134> (accessed July 17, 2004).

¹² See <http://www.arizonabev.com/csr/history.asp> (accessed July 17, 2004).

¹³ See <http://www.welchs.com/products/singleserve.html> (accessed July 17, 2004).

¹⁴ Coca-Cola recently announced that it would have dual-column labels on soft drinks >12 oz. and ≤ 20 oz. CSPI believes that it is inappropriate and confusing to list RACC nutrient values for products that are almost always consumed as one serving. Also, Coca-Cola apparently does not plan to label its 24 oz. bottles as single servings (or with dual-columns), even though those products are marketed as single servings. FDA action is needed to ensure that all companies use the same labeling system so as to minimize consumer deception.

¹⁵ “Large-size candy: Can vending follow success of retail?” *Automatic Merchandiser*, May 2002. http://www.amonline.com/new/article_archives.asp?action=details&magarticle_id=564 (accessed July 29, 2004).

of the package how many servings the package contains.¹⁶ Kraft has already begun distribution of “Ritz Chips” bearing nutrition facts based on both the RACC and the entire package.¹⁷ Also, PepsiCo has said that it will improve the labeling of its over-sized single-serving packages.¹⁸

But, Kraft and Frito-Lay aside, many 2-oz., 3-oz., and 4-oz. packages produced by other companies that can reasonably be consumed at a single sitting are still being labeled as containing multiple servings. FDA regulations are needed to ensure that all snack foods are labeled in a useful, clear, and consistent manner.

IV. Muffins and Similar Baked Goods

Muffins, coffee cakes, doughnuts, Danishes, and other sweet baked goods have a reference amount of 55 g (2-oz.), but many individually packaged baked goods in convenience stores contain two to three times that amount. Despite FDA statements in the Preamble that it considers over-sized packages of muffins to be examples of products that should be labeled as containing a single serving, many manufacturers continue to label their baked goods and “on-the-go” packages as containing multiple servings.

For example:

- Otis Spunkmeyer Co. lists its 4-oz. muffin as providing two servings.
- Bon Appetit Bakery, which sells single-serve baked goods in many convenience stores, advertises its 5-oz. French Sweetie pastry as a “meal in itself” while labeling the item as two servings.¹⁹

The FDA should take enforcement action to stop such labeling.

V. Conclusion

CSPI believes that adoption of the recommendations listed above would enable the FDA to utilize its authority to strike a small blow against obesity in the most expedient fashion. FDA should require, not just encourage, companies to correct the misbranding of large single-serving containers and to label their products in the most accurate and informative manner to consumers.

¹⁶ See http://www.kraft.com/responsibility/nhw_portionsizes.html (accessed October 1, 2004).

¹⁷ Although the RACC for snack foods is 28g Kraft lists 29g as the serving size. We assume this is a typographical error.

¹⁸ McKay B. “Coke and Pepsi plan to revise nutrition data on products.” *Wall Street Journal*, October 20, 2004, p. B5.

¹⁹ See <http://www.bonappetitbakery.com> (accessed July 15, 2004).

Sincerely,

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