



GENERAL MILLS

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May 14, 2009

Tyra S. Wisecup
Compliance Officer
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401

Re: Initial Response to Warning Letter of May 5, 2009

Dear Ms. Wisecup:

This letter conveys the initial response of General Mills to the Warning Letter dated May 5, 2009, regarding the label and other information for our Cheerios® Toasted Whole Grain Oat Cereal.

General Mills takes seriously its responsibilities in providing to consumers truthful, nonmisleading, and substantiated information about the relationship between diet and health, and in complying with applicable regulatory requirements. Our company strongly supports FDA's Consumer Health Information for Better Nutrition Initiative announced in 2003, and its "twin goals of making available better, easily understood, up-to-date scientific information about how dietary choices can affect health, as well as encouraging companies to compete based on health and nutrition consequences, in addition to such non-health-related features of products like taste and ease of preparation."¹ Towards that end, General Mills invests millions of dollars in scientific research, including clinical studies, about the relationship between diet and health. Where appropriate and consistent with FDA requirements and other governing law, General Mills uses its marketing expertise to convey to consumers, in ways they can readily access and understand, diet and health information supported by scientific evidence and by government dietary guidelines to help consumers make healthy dietary choices.

It is from this perspective that General Mills carefully crafted the communications that are the subject of FDA's warning letter - the claims on the Cheerios® label that have been on the market for two years, and the www.wholegrainnation.com website, which was launched in 2007. As

¹ FDA Press Release, "FDA to Encourage Science-based Labeling and Competition for Healthier Dietary Choices," July 10, 2003, available at <http://www.fda.gov/bbs/topics/INEWS/2003INew00923.html>.

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articulated below, General Mills holds a different view from FDA regarding the statements in these materials, and respectfully disagrees with the agency that these label claims and website violate the Federal Food, Drug, and Cosmetic Act (FDCA). As you are aware, we will also pursue discussions directly with CFSAN regarding this matter. (b) (4)

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Cheerios® in a low fat, reduced calorie diet. In addition, there are broader public health policy issues raised by the letter.

I. The Cholesterol Statements on the Cheerios® Package Are Truthful and Substantiated and Are Not Unlawful Disease Claims

General Mills has presented the statements about cholesterol on the Cheerios® label as (1) statements of fact reporting the results of a clinical trial, and (2) statements authorized as part of the FDA-approved soluble fiber/coronary heart disease (CHD) health claim under 21 C.F.R. § 101.81 (d)(2)-(3), which allows additional claim language explaining that the mechanism by which soluble fiber reduces CHD risk is through the intermediate link of serum cholesterol. Accordingly, the cholesterol statements do not suggest that Cheerios® is intended for use in treating hypercholesterolemia, nor do they violate the provisions of the soluble fiber/CHD health claim regulation relating to reducing the risk of CHD. The integrated message of Cheerios® has for more than a decade been about reducing the risk of heart disease, as evidenced by the use of the FDA-approved soluble fiber/CHD health claim and the graphic depictions of heart symbols on the package (e.g., heart-shaped bowl, etc.).

A. Factual Description of a Clinical Trial Does Not Make Cheerios® a Drug

The Cheerios® label bears truthful, nonmisleading factual statements reporting the results of one of the clinical trials conducted on Cheerios® and published in a peer-reviewed scientific journal² General Mills has presented this information in an integrated fashion on its Cheerios® package because we know that consumers do read cereal boxes. Because we are aware that consumers read the back and side panels as well as the principal display panel (PDP) of the cereal box, the company devoted a considerable portion of this valuable label space to discussing this clinical trial. In this manner, General Mills employed both consumer-friendly, easy-to-understand summary information about the trial on the front panel along with a prominent referral to the additional contextual information on the back panel: the modest 4% reduction in "bad" cholesterol levels shown in the study, the quantity of cereal consumed per day as part of a diet low in saturated fat and cholesterol, and the results seen after six weeks.

² Jolmston, L., *et al.* Cholesterol-lowering benefits of a whole grain oat ready-to-eat cereal. *NIH Clin Care* 1998; 1:6-12.

These representations are substantiated not only by the study cited on one of the Cheerios® packages,} but also by two additional clinical trials published in peer-reviewed scientific journals' These three studies were conducted by two different researchers over a number of years and with varying populations, yet consistently showed that consuming 3 cups of Cheerios® daily for four to six weeks as part of a low fat, low cholesterol diet reduced LDL cholesterol by more than 4%. Moreover, these clinical trials are consistent with the surrounding body of scientific literature examining the effects of soluble fiber from oats on cholesterol levels, including many studies that were cited by FDA in promulgating the soluble fiber/CHD health claim.⁵ In light of this ample scientific evidence, the cholesterol statements on the Cheerios® package were found to be truthful and substantiated by the National Advertising Division of the Council of Better Business Bureaus (NAD), which evaluated this label and related advertising in 2007 as part of its routine monitoring program⁶

General Mills believes that consumers are entitled to specific information about the relationship between their diet and their health, as did Congress in requiring that health claims be stated "so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.,⁷ By reporting the results of clinical trials on our product label, we aim to help convey such specific and relevant health information to consumers in a manner that meets this Congressional intent and that is much more accessible than simply publishing the results in a scientific journal consumers are not likely to see. Conveying such factual descriptions of scientific evidence about the relationship between diet and health is not only consistent with FDA's Consumer Health Information for Better Nutrition Initiative, but also is protected by the First Amendment. It is well settled that the First Amendment protects the rights of food marketers to communicate truthful, nonmisleading, and

} See *id.*

4 Reynolds, H., et al. Whole Grain Oat Cereal Lowers Serum Lipids. *Top Clin Nutr* 2000; 15(4):74-83; Karmally, W., et al. Cholesterol-Lowering Benefits of Oat-Containing Cereal in Hispanic Americans. *J Am Diet Assoc* 2005 Jun; 105(6):967-70. General Mills also recently submitted for publication the report of its latest clinical trial, which found that including 3 cups of Cheerios® each day in a reduced calorie and reduced fat diet lowers LDL cholesterol 10.7% in one month. This latest addition to the body of literature continues to show the consistency of the scientific evidence on this issue.

, See 61 Fed. Reg. 296 (January 4, 1996) (Proposed Rule).

⁶ General Mills, Inc. (Cheerios Cereal), # 4683, *NAD Case Reports* (June 15, 2007). NAD's only recommendation after reviewing these materials was that General Mills add a reference to a low cholesterol diet, because the participants in the substantiating studies followed a diet that was both low in cholesterol and low in fat. General Mills subsequently modified its labels and advertising to include this reference.

⁷ FDCA § 403(r)(3)(B)(iii) (21 U.S.C. § 343(r)(3)(B)(iii)).

substantiated health-related information to consumers, including a strong presumption against the government's ability to suppress such communications⁸ These factual statements about the clinical trial results simply convey useful information to consumers and do not constitute or reveal an intent by General Mills to market Cheerios® as a drug.

B. Cholesterol Statements are Consistent with FDA's Soluble Fiber/CHD Health Claim Regulation

In addition to presenting the results of the clinical study, the cholesterol information on the PDP is related to and permitted under the FDA-approved soluble *fiber/CHD* health claim, which also appears on that panel. 21 C.F.R. § 101.81(d)(2)-(3). Those regulatory provisions permit the use of optional information that the mechanism of action by which soluble fiber reduces the risk of CHD is through cholesterol reduction. Use of the optional language does not constitute a separate disease claim nor does it make the product a drug. In part because of the length of the model health claim, General Mills believes that the banner with the cholesterol statement on the Cheerios® label attracts consumers to important information about the relationship between diet and health more than use of the model claim alone. The banner thus helps draw attention to the claim that FDA has agreed can and should be conveyed to consumers to empower them to make healthy dietary choices. Again, because General Mills knows its consumers view the Cheerios® package as a whole, the company considers the cholesterol statements and the model health claim language on its label to be integrated and mutually reinforcing⁹

The statements on the Cheerios® label about lowering cholesterol 4% in 6 weeks are not statements attributing a degree of risk reduction for CHD, as is disallowed under the health claim regulation at 21 C.F.R. § 101.81 (c)(2)(E). That provision plainly was not intended to preclude companies from reporting factual clinical results. To the contrary, in promulgating the regulation, FDA explained that the claims should "not attribute any degree of risk reduction of CHD to consumption of oat products. None of the studies that the agency reviewed provide a basis for determining the percent reduction in risk of CHD likely from consuming diets high in oat products."¹⁰ Thus, FDA intended to prevent unsubstantiated claims about CHD risk reduction. The

⁸ See, e.g., *Pearson v. Shalala*, 130 F. Supp.2d 105, 110 (D.D.C. 2001); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

⁹ We note as well that the "model" health claim is exactly that - a model. As long as the health claim meets the requirements of the applicable regulations, it is not required to use the precise language provided by way of example in the model claim. Moreover, on the Cheerios® box, the language appears on the same panel and in close proximity and without intervening material. Given the way in which consumers read cereal boxes, as discussed above, it is very likely that all of the information on the PDP, for example, will be read by the consumer.

¹⁰ 61 Fed. Reg. at 306.

4% cholesterol reduction claims on the Cheerios® label are not claims about the degree of reduction of CHD risk, and are firmly substantiated by the clinical trials.

As FDA has made clear, CHD is a multifactorial disease that is not attributable to cholesterol levels alone. A statement about a 4% reduction in LDL cholesterol levels does not convey to consumers a specific degree of risk reduction. It is, however, a legitimate part of the message of a reduced risk of CHD generally – a message FDA has authorized for products, like Cheerios®, meeting the criteria for the FDA-approved soluble fiber/CHD health claim. The statement about the percentage LDL cholesterol reduction is a way to communicate to consumers in a concrete and substantiated way that they can readily understand that this is part of the factual science undergirding the health claim, and is made in conjunction with the complete model health claim language. The percentage statements thus do not characterize the level or degree of reduction of CHD risk and are therefore not prohibited under 21 C.F.R. § 101.81(c)(2)(E). In fact, the position espoused in FDA's letter seems to directly contradict the Agency's public positions and guidances allowing statements of fact.

In sum, the cholesterol statements on the Cheerios® label provide truthful, nonmisleading, and substantiated factual information to consumers in an understandable way that is readily accessible to them. In this manner, the label is intended to help consumers make healthy dietary choices, consistent with the public health goals FDA has expressed through its Consumer Health Information for Better Nutrition Initiative, and within the applicable confines of both FDA's regulations and Congress' stated intent in authorizing health claims on food. The cholesterol statements do not suggest that this breakfast cereal is intended to treat hypercholesterolemia, and therefore do not make Cheerios® an unapproved new drug, but rather help to explain the mechanism by which the soluble fiber in Cheerios® can help reduce the risk of heart disease, as expressly permitted in the health claim.

II. The Statements on the Website are Dietary Guidance, Not Health Claims

As an initial matter, General Mills respectfully disagrees with FDA that the content on its website, www.wholegrainnation.com is "labeling" simply because the web address appears on the Cheerios® label. This website is an educational site providing general dietary guidance to assist consumers in identifying whole grain foods and incorporating them into healthy diets. This information helps consumers to implement current public health recommendations such as the Dietary Guidelines for Americans (Dietary Guidelines). The Dietary Guidelines include "Whole Grains" among the "Food Groups to Encourage," because of their benefits in reducing the risk of CHD and other chronic diseases, and urge consumers to make at least half of their grain servings whole grain.¹¹

¹¹ See Dietary Guidelines, Chapter 5 (Food Groups to Encourage) and Chapter 7 (Carbohydrates), available at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf>.

In the context of this educational website, the statements FDA quotes are not unauthorized health claims. Rather, they are dietary guidance statements meeting the criteria that FDA has articulated for such statements. FDA has explained clearly the distinction between health claims and dietary guidance statements in numerous formal and informal guidance documents. Health claims contain two basic elements: a substance, and a disease or health-related condition. By contrast,

dietary guidance statements may make reference to a disease or substance, but not both. For example, dietary guidance statements might focus on general dietary patterns or practices and broad categories of foods, rather than a specific substance. . . .

FDA concluded that a claim about the benefits of a broad class of foods (e.g., fruits or vegetables) that does not make an express or implied connection to a substance found in that class of foods would not constitute an implied claim, and that such a claim is not a health claim. Rather, such a statement would be dietary guidance because it is not expressly or impliedly about a substance.¹²

FDA states that an example of a dietary guidance statement is: "Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases."¹³

The following statements that FDA cited from our educational www.wholegrainnation.com website are plainly dietary guidance statements because, in this context, they refer to dietary patterns including a broad class of whole grain foods, rather than to a substance:

- "Heart-healthy diets rich in whole grain foods can reduce the risk of heart disease."
- "Including whole grain as part of a healthy diet may . . . [h]elp reduce the risk of certain types of cancers. Regular consumption of whole grains as part of a low-fat diet reduces the risk for some cancers, especially cancers of the stomach and colon."

Our website plainly clarifies that these statements are not implied claims about the specific dietary substance, fiber. Our webpage on that site entitled, "Whole Grain is More than Just Fiber," emphasizes that whole grain foods provide benefits that are distinct from those attributable to the varying fiber content in each type of whole grain food.¹⁴

¹² 68 Fed. Reg. 66040, 66046 (November 25, 2003) (ANPR, Food Labeling: Health Claims; Dietary Guidance).

¹³ *Id.* See also *FDA/CFSAN*, "Dietary Guidance Message About Fruits and Vegetables," July 29, 2003; revised August 28, 2003, available at <http://www.cfsan.fda.gov/~dms/lab-dg.html>.

¹⁴ See <http://www.eatbetteramerica.com/wholegrainnation/Benefits/MoreThanFiber.aspx>.

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Because the website statements cited in the warning letter are dietary guidance, and not health claims, they are not improper iterations of the health claims authorized under 21 C.F.R. §§ 101.76 and 101.77, or section 403(r)(3)(C) of the FDCA. As dietary guidance statements, these claims require no FDA prior approval, but rather need only be truthful and nonmisleading,¹⁵ which they are. FDA explained that, "as part of its recent Better Nutrition Information for Consumer Health Initiative, [FDA] recognized that scientifically sound and non-misleading dietary guidance statements may be useful to consumers when placed on food labels."¹⁶ General Mills wholly agrees, and believes that such dietary guidance statements are also useful to consumers when made on health and nutrition education websites such as our www.wholegrainnation.com site.

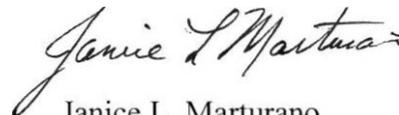
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We would appreciate the opportunity to discuss further this matter of important public health significance. Because the warning letter and our response raise issues that General Mills considers appropriate to discuss with FDA headquarters, we also intend to address this matter with relevant personnel there, as you know from our reported contacts with CFSAN. As noted earlier, part of our

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including this whole grain oat cereal in a low fat, reduced calorie diet.

Sincerely,



Janice L. Marturano
Vice President, Public
Responsibility and Deputy
General Counsel

cc: Stephen Sundlof, Director, CFSAN
Jennifer Thomas, CFSAN
Michael Landa, OCC

¹⁵ See, e.g., FDN CFSAN Guidance for Industry, "FDA's Implementation of 'Qualified Health Claims': Questions and Answers," May 12, 2006 (FDA Qualified Health Claims Q&A Guidance), available at <http://www.cfsan.fda.gov/~dms/ghcgagui.html>.

¹⁶ *Id.*