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BY CERTIFIED MAIL

Felicia Satchell, Staff Director
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products Labeling and Dietary Supplements (HFS-820)
5100 Paint Branch Parkway
College Park, MD 27040

Re: Consumer Complaint Regarding Unauthorized Health Claims on Labeling

Dear Ms. Satchell:

On June 9, 2005, the Physicians Committee for Responsible Medicine (PCRM) filed a citizen petition, docket number 2005P-0224/CP1, with the Food and Drug Administration, requesting that FDA take administrative action against certain dairy product manufacturers for labeling their products with false, misleading, and unauthorized health claims that milk consumption promotes weight and fat loss. PCRM now formally withdraws that petition and files this consumer complaint, requesting that FDA take enforcement action against The Dannon Company, Inc., General Mills, Inc., and McNeil Nutritionals, LLC (dairy product manufacturers). PCRM also requests that FDA incorporate the contents of the withdrawn petition and its exhibits as supporting documentation to this consumer complaint.

The dairy product manufacturers have made and continue to make health claims on the labeling of their food products that consuming three servings of dairy per day leads to weight and fat loss. They have done so without first obtaining the statutorily required FDA approval for the inclusion of health claims on labels. These products therefore are misbranded, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). The products also are misbranded because the labels are false and misleading and fail to disclose material facts.

I. Dairy Product Manufacturers' Dairy Products Are Misbranded Because Approval for the Dairy/Weight Loss-Obesity Prevention Health Claims Has Not Been Sought or Obtained

Dairy product manufacturers basically make two obesity-prevention claims: that the consumption of dairy products will cause *weight* loss and that the consumption of dairy products will cause *fat* loss. These claims are “health claims” that have not been approved by FDA.

“Health claims” characterize the relationship between a substance and its ability to reduce the risk of a disease or health-related condition.¹ A “substance” means a specific food or component of food.² “Disease” or “health-related condition” means damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning.³ Milk and yogurt are “substances” because they are specific foods. Calcium is also a “substance” because it is a component of milk and yogurt. Moreover, obesity is a disease and a health-related condition.⁴ Thus, the dairy/weight and fat loss claims are health claims that must be approved by FDA.

Section 403 of the FFDCFA provides two methods through which FDA allows food product manufacturers to make health claims in food labeling. In the first method, the manufacturer may make a health claim if the claim is authorized by FDA regulations⁵ upon a finding of “significant

¹ 21 C.F.R. § 101.14 (2005).

² *Id.* § 101.14(a)(2).

³ *Id.* § 101.14(a)(5).

⁴ Recently, the IRS began recognizing obesity as a disease, *see* IRS, DEP’T OF TREASURY, PUBLICATION 502, and Medicare redefined obesity as an illness, Marguerite Higgins, *Obesity Deemed an Illness*, WASH. TIMES, July 15, 2004 (attached to petition as Ex. 14), <http://www.washingtontimes.com/business/20040715-104805-1408r.htm> (last visited Apr. 28, 2005). The *Surgeon General’s Call To Action To Prevent and Decrease Overweight and Obesity* noted that the health consequences of overweight and obesity is “a public health issue that is among the most burdensome faced by the Nation This burden manifests itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. The burden is not trivial. Studies show that the risk of death rises with increasing weight. Even moderate weight excess . . . increases the risk of death.” *See* HHS, THE SURGEON GENERAL’S CALL TO ACTION TO PREVENT AND DECREASE OVERWEIGHT AND OBESITY 1 (2001) (attached to petition as Ex. 1), <http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf> (last visited May 31, 2005). Moreover, the Surgeon General noted, overweight and obesity are associated with premature death, type 2 diabetes, heart disease, stroke, hypertension, gallbladder disease, osteoarthritis, sleep apnea, asthma, breathing problems, and cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast), among other health dysfunctions. *Id.* at 9 tbl.1.

⁵ 21 U.S.C. § 343(r)(3)(A)(i) (2005).

scientific agreement.”⁶ This “significant scientific agreement” standard is based on a body of sound and relevant scientific data and is intended to provide a high level of confidence that the validity of the substance/disease relationship is not likely to be reversed by new and evolving science.⁷ Therefore, these “unqualified” health claims require significant scientific agreement based on the totality of publicly available scientific evidence.⁸ The second method allows a manufacturer to label a food product with a health claim that is based on an authoritative claim by certain scientific bodies of the federal government or the National Academy of Sciences or any of its subdivisions.⁹

Recently, FDA issued interim regulatory guidance¹⁰ allowing lower standards of proof for the substantiation of substance/disease relationships that are the subject of “qualified” health claims.¹¹ Under the interim guidelines, qualified health claims are appropriate “when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition.”¹² Pursuant to this guidance, food manufacturers may petition for the right to use qualified health claims that are worded (qualified)

⁶ The Secretary must first determine “based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.” *Id.* § 343(r)(3)(B)(i). *See also* 21 C.F.R. § 101.14(c) (2005).

⁷ CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY: SIGNIFICANT SCIENTIFIC AGREEMENT IN THE REVIEW OF HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (1999), <http://www.cfsan.fda.gov/~dms/ssaguide.html> (Dec. 22, 1999).

⁸ *Id.*

⁹ 21 U.S.C. § 343(r)(3)(C)(i) (2005).

¹⁰ *See* CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, INTERIM PROCEDURES FOR QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL HUMAN FOOD AND HUMAN DIETARY SUPPLEMENTS (2003), <http://www.cfsan.fda.gov/~dms/hclmgu3.html> (last updated Nov. 10, 2003). While these interim guidelines are not legally enforceable because they have not been promulgated through notice-and-comment rulemaking, they do set forth the Agency’s intended course of action for regulations. As of this date, FDA has not issued proposed or final regulations on this subject, but it did issue an Advanced Notice of Proposed Rulemaking. *See* Food Labeling: Health Claims; Dietary Guidance, 68 Fed. Reg. 66,040 (Nov. 25, 2003) (to be codified at 21 C.F.R.).

¹¹ FDA adopted this policy in response to court rulings establishing that consumers have a First Amendment right to truthful health information even if that information is not supported by significant scientific agreement. *See* *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

¹² CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, CLAIMS THAT CAN BE MADE FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (2003), <http://www.cfsan.fda.gov/~dms/hclclaims.html> (last updated Sep. 24, 2003).

in such a way that consumers are not misled about the nature of the supporting science.¹³ FDA will approve a petition for a qualified health claim only after performing a scientific review of the claim and determining what accompanying qualifying language must be included before the claim may be used.¹⁴

FDA has not authorized the dairy product manufacturers' health claims. There has been no authoritative claim by a scientific body of the federal government or the National Academy of Sciences on which to base such health claims. In fact, the Dietary Guidelines Advisory Committee, which was appointed by the Departments of Health and Human Services and Agriculture to assist in the development of the *2005 Dietary Guidelines for Americans*, found that "there is insufficient evidence" linking the consumption of "milk products and the management of body weight."¹⁵ Furthermore, FDA has not authorized, as unqualified or qualified, health claims that consuming three servings of dairy products or three servings of dairy calcium—or for that matter, calcium from any source—leads to a greater likelihood of weight loss or fat loss, nor have the dairy product manufacturers petitioned FDA for either a qualified or unqualified health claim related to the dairy/weight and fat loss hypothesis.¹⁶ Even if the dairy product manufacturers had petitioned for approval to make these health claims, FDA would undoubtedly have denied such petitions because the scientific evidence in support of the claims would fail to meet even the lowest standard set forth by FDA.¹⁷ Factoring in the failure of dairy product manufacturers to seek approval before placing these health claims on food product labeling, the absence of an FDA determination that these claims are scientifically valid, and the absolute lack of reliable scientific support for these claims, FDA must find that the products labeled with such health claims are misbranded, in violation of section 301 of FFDCa.

¹³ *Id.*

¹⁴ CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, A FOOD LABELING GUIDE—APPENDIX C (2003), <http://www.cfsan.fda.gov/~dms/flg-6c.html> (last updated May 13, 2003) (explaining the review process in sections B.4, B.7, and B.8).

¹⁵ USDA, DIETARY GUIDELINES ADVISORY COMMITTEE, 2005 REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS D-19 (2004), http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D6_SelectedFood.pdf (Aug. 19, 2004).

¹⁶ This conclusion is based on a review of FDA's Web site, which lists all petitions submitted for approval of both unqualified and qualified health claims. *See* FDA, DOCKETS MANAGEMENT, at <http://www.fda.gov/ohrms/dockets/> (last visited July 28, 2005); FDA, QUALIFIED HEALTH CLAIMS, at <http://www.cfsan.fda.gov/~dms/lab-qhc.html#petition> (last visited July 28, 2005).

¹⁷ *See* CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, INTERIM EVIDENCE-BASED RANKING SYSTEM FOR SCIENTIFIC DATA (2003), <http://www.cfsan.fda.gov/~dms/hclmngui4.html> (last updated Nov. 10, 2003).

II. Dairy Product Manufacturers' Dairy Products Are Misbranded Because Their Labels Carry Health Claims that Are False and Misleading to the Reasonable Consumer

a. Dairy Product Manufacturers' Dairy Products Are Misbranded Because the Representations on Their Labels Are False

A food product is misbranded if any one representation on its labeling is either false or misleading.¹⁸ The labels on several of the products produced by the dairy product manufacturers expressly claim that consuming at least three servings of dairy products every day on a reduced-calorie diet will result in greater weight and fat loss than just cutting calories alone.¹⁹ The labels further make the implied claim that it is the special mix of nutrients in dairy products that makes this weight and fat loss happen. In other words, the labels convey to the consumer the false message that simply adding dairy products to one's diet will cause weight and body fat loss.

The health claims are simply false—there is no acceptable scientific basis that lends any credence to them. Dairy product manufacturers cite what they characterize as “recent research”²⁰ or “recent studies”²¹ that they assert support this claim. The body of scientific evidence, including emerging science, however, supports precisely the opposite conclusion: studies show that adding dairy products to the diet does nothing whatsoever for weight control; in some cases, it encourages weight *gain*. As explained in great depth in withdrawn petition 2005P-0224/CP1, the diet actually cited and promoted by dairy product manufacturers requires the consumer to reduce daily calorie intake by 500 calories. In fact, that is all there is to the diet: reduce your calorie intake by 500 calories. Any food could be substituted for dairy products in this scenario—french fries for example—and there would be similar weight loss. It is the reduction in calories that causes weight loss, *not the dairy products*. Dairy product manufacturers have, however, disguised the required diet technique with false health claims about the role that dairy products play in losing weight and body fat. As such, all labeling bearing the dairy weight loss claim is false and FDA must find that the products labeled with such health claims are misbranded, in violation of section 301 of FFDCa.

¹⁸ 21 U.S.C. § 343(a) (2005). *See also* United States v. Hoxsey Cancer Clinic, 198 F.2d 273, 281 (5th Cir. 1952) (“It was not necessary for the Government to prove that each and every representation in the booklet was false or misleading. The statute seeks to prevent labeling which is false or misleading in any particular.”).

¹⁹ Ex. 4 (“3–4 servings daily (providing at least 600 mg of calcium per day) as part of a high-calcium, reduced calorie diet.”); Exs. 5–6 (“As part of a reduced-calorie diet, 3 servings daily of dairy foods, like Yoplait, supports more weight loss than cutting calories alone.”); Exs. 7–10 (“3 servings of dairy a day in a reduced-calorie diet supports weight loss.”).

²⁰ Exs. 5–6.

²¹ Exs. 7–10.

b. Dairy Product Manufacturers' Dairy Products Are Misbranded Because the Representations on Their Labels Are Misleading to the Average Consumer

Labeling is considered misleading if it fails to reveal facts that are material either in light of other statements or suggestions on the label or with respect to consequences that result under the prescribed or customary use of the food.²² FDA employs the “reasonable consumer” standard for assessing whether a food label is misleading.²³ Although FDA has not published a deception policy statement, it favorably cited the *FTC Policy Statement on Deception*²⁴ when it adopted the reasonable consumer standard.²⁵ This policy considers a health claim from the perspective of a consumer acting reasonably under the circumstances.²⁶ Under the policy, a statement that can be reasonably interpreted in a misleading way is deceptive, even though other, non-misleading interpretations may be equally possible.²⁷ Furthermore, an interpretation is presumed reasonable if it is the claim the food product manufacturer attempted to convey.²⁸ Here, there is ample evidence that the reasonable consumer would interpret the health claims to mean that consuming at least three servings of dairy products every day will result in weight and fat loss.

The labels are misleading because they are ambiguous as to whether a calorie-restricted diet is part of the weight loss effect and as to the severity of the required calorie restriction. A reasonable consumer would have the impression that he or she simply needs to “watch calories,” when in reality, calorie intake would have to be decreased drastically to achieve an effect on weight loss. The only studies that purport to show a cause and effect relationship were based on a diet that cut calories by 500 per day, which is about one-fourth of the total calorie intake of the average person. It is extremely unlikely that the reasonable consumer would be willing to replicate the conditions of the study (24 ounces of milk per day, 500 calories per day restriction for 6 months), which may be why the dairy product manufacturers do not plainly disclose this information. Thus, the labels fail to reveal facts that are material with respect to the change in weight and fat that will result under customary use of the food product. Additionally, the labels fail to reveal the requirements of the actual diet that leads to weight loss—facts that clearly are

²² 21 U.S.C. § 201(n) (2005); 21 C.F.R. § 1.21(a) (2005).

²³ See Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002, 78,003 (Dec. 20, 2002) (adopting the “reasonable consumer” standard to make FDA’s regulation of food labeling consistent with FTC’s regulation of advertising for the same products and to ensure that FDA’s approach is consistent with First Amendment case law).

²⁴ FTC, FTC POLICY STATEMENT ON DECEPTION (1983) (attached to petition as Ex. 12), <http://www.ftc.gov/bcp/policystmt/ad-decept.htm> (last visited Apr. 28, 2005).

²⁵ See Guidance for Industry, *supra* note 26, at 78,003–04.

²⁶ FTC POLICY STATEMENT ON DECEPTION, *supra* note 27.

²⁷ *Id.*

²⁸ *Id.*

material in light of the representations regarding weight loss made on the labels. Accordingly, the labels are misleading.

Moreover, the distortion and omission of material facts about the large body of science that contradicts the weight loss hypothesis gives a false and misleading impression to the reasonable consumer about the scientific support for these health claims. Dairy product manufacturers also fail to reveal their role in the very studies they cite in support of their claims. For instance, the one and only yogurt study listed on the Yoplait Web site was funded by Yoplait's manufacturer, General Mills.²⁹ Several other studies cited on the aforementioned Web sites were funded by the National Dairy Council, which promotes demand for U.S. dairy products.³⁰ Thus, consumers reasonably, yet mistakenly, believe that the studies behind the health claims have been performed and verified by detached and unbiased sources. Because the consumer reasonably assumes from the health claims a set of facts opposite to that which actually exists, disclosure of the full body of relevant science is necessary to prevent the claims from being misleading. All labeling bearing the dairy weight loss claim is therefore misleading to the reasonable consumer, and FDA must find that these food products are misbranded, in violation of section 301 of FFDCa.

III. Lactaid's Whole Milk is Misbranded Because it Has Disqualifying Nutrient Levels

FDA regulations disqualify the making of a health claim on food labels for foods with more than 13 grams of fat, 4 grams of saturated fat, or 60 milligrams of cholesterol per serving.³¹ Lactaid's Whole Milk has 5 grams of saturated fat per serving.³² Because it contains a disqualifying nutrient level, no health claim can be made on the labeling for the product unless a regulatory exception is provided.³³ No such exception exists here.³⁴ Accordingly, FDA must find that Lactaid's Whole Milk product is misbranded, in violation of section 301 of FFDCa.

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²⁹ Zemel MB, Richards J, Mathis S, Milstead A, Gebhardt L, Silva E. Dairy augmentation of total and central fat loss in obese subjects. *Int J Obes.* 2005;29:391-397 ("This research was supported by the Bell Institute of Health and Nutrition, General Mills Inc."). The Web site cites the abstract of this study.

³⁰ See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, THE INTEGRITY IN SCIENCE DATABASE (2005) (attached to petition as Ex. 15), at <http://www.cspinet.org/integrity/> (last visited May 31, 2005).

³¹ 21 C.F.R. § 101.14(a)(4) (2005).

³² Ex. 7.

³³ 21 C.F.R. § 101.14(a)(4) (2005).

³⁴ See *id.* §§ 101.70–101.83.

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Literally millions of Americans are exposed to the dairy weight loss promotion on a daily basis. While the promotion has been effective at conveying its message, the message is unequivocally deceptive, misleading, and dangerous. Several dairy product manufacturers now deliver this dangerous message in the form of unauthorized false and misleading health claims in the labeling of several food products that are nationally distributed and widely available in neighborhood supermarkets. Given the tremendous public saturation of the weight loss promotion, a stop is urgently needed to any further dissemination of fraudulent health claims regarding the purported weight and fat loss benefits of dairy products.

For all of the above reasons, PCRM requests that FDA take the following enforcement actions:

- 1) Institute an examination or investigation into the labeling of certain food products made and distributed by the dairy product manufacturers that make unauthorized health claims regarding the purported weight and fat loss benefits of dairy products, pursuant to 21 U.S.C. § 372(a);
- (2) Declare food products made and distributed by the dairy product manufacturers and bearing labels with unauthorized health claims regarding the purported weight and fat loss benefits of dairy products misbranded;
- (3) Institute a voluntary recall, court-ordered injunction, or seizure of misbranded food products made and distributed by the dairy product manufacturers, pursuant to 21 U.S.C. § 332(a), 21 U.S.C. § 334(a)(1), 21 C.F.R. § 7.40, and 21 C.F.R. § 7.45; and
- (4) As a corrective measure, require material disclosure of affirmative facts about the lack of a scientific connection between dairy consumption and weight and fat loss on future products made and distributed by the dairy product manufacturers, pursuant to 21 U.S.C. § 371 and 21 C.F.R. § 1.21(b).

Very truly yours,

Mindy Kursban

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cc: Ms. Jenny Little, Division of Dockets Management