

August 4, 2004

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

Dear Acting Commissioner Crawford:

The Center for Science in the Public Interest would like to bring to your attention deceptive labeling of Newman's Own organic cookies, including all varieties of Champion Chip Cookies, Newman-O's, and Alphabet Cookies, as well as Pop's Corn microwave popcorn.² Those products are made with palm oil, about which product labeling provides information, some of it misleading. We urge the FDA to halt the deceptive labeling under its misbranding authority embodied in sections 403(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 343 and 321(n).³

Newman's Own labels (attached) make the following misleading statements:

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¹ The Center for Science in the Public Interest is a nonprofit organization based in Washington, D.C. It is supported by about 850,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971. CSPI has long been concerned about the use of palm and other tropical oils and partially hydrogenated vegetable oil in the food supply.

² Our criticisms of Newman's Own labeling do not detract from our admiration of the company's charitable mission.

³ Section 403(a) of the FFDCA provides that a food is misbranded if "its labeling is false or misleading in any particular." Section 201(n) of the FFDCA says that "in determining whether the labeling ... is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling...fails to reveal facts material in the light of such representations or material with respect to consequences which result from the use of the article to which the labeling ... relates ... under such conditions of use as are customary or usual." [italics added]

• "Organic Palm Oil is not hydrogenated," "contains no trans-fatty acids," and "is lower in saturated fat than butter and has no cholesterol." While we agree that palm oil is not hydrogenated (and is less harmful than the same amount of a typical shortening made with partially hydrogenated oil) and does not contain trans fat or cholesterol, the claim is misleading because it strongly implies that palm oil is positively healthful. Saying that palm oil is lower in saturated fat than butter is misleading, because butter is higher in cholesterol-raising fatty acids (particularly palmitic acid) than almost any other fat. Just being lower in saturated fat than butter does not ensure that a fat (like palm oil) is healthful.

The ratio of total cholesterol:HDL cholesterol is viewed as an excellent indicator of heart-disease risk (the higher the ratio, the higher the risk).⁴ According to a meta-analysis by Mensink et al.,⁵ palm oil leads to almost as unfavorable changes in serum cholesterol (total:HDL) as butter and is considerably less healthful than the average U.S. dietary fat. Similarly, making favorable comparisons to a typical partially hydrogenated oil is misleading, because, again, just because palm oil is not as bad as the absolutely worst oil does not make palm a healthful and desirable choice. Palm oil is less healthful than numerous other oils (such as olive, corn, soy, canola, sunflower, safflower, and high-oleic versions of those oils), but comparisons to those oils would have been counterproductive to Newman's Own goal of encouraging the purchase of its products.

We note that it is possible to make cookies with oils that are more healthful than either palm oil or partially hydrogenated oil.⁶

• "Of the three tropical oils, Palm oil is 50% saturated while Palm Kernel Oil is 86%, and Coconut Oil is 92% saturated." Many people understand that saturated fat is unhealthful, but the Newman's Own statement is misleading (though literally true)

⁴ "The total:HDL cholesterol ratio has been shown to be an important risk factor for CHD." Panel on Macronutrients, Institute of Medicine. Dietary reference intakes: energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein and amino acids. Institute of Medicine, National Academies. 2002. Page 11-7.

⁵ Mensink RP, Zock PL, Arnold DM, et al. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. Am J Clin Nutr. 2003;77:1146-55.

⁶ Examples include: Frookie Frookwich Chocolate Sandwich Cookies (canola oil); Country Choice Sandwich Cremes (high-oleic sunflower and/or safflower); 365 (Whole Foods) Sandwich Cremes (canola); Frookie Frookwich Vanilla Sandwich Cookies (soybean); Country Choice Vanilla Sandwich Cremes (oleic safflower); Country Choice Vanilla Wafers (oleic sunflower and/or oleic safflower); Country Choice Oatmeal Raisin (canola, high-oleic sunflower and/or high-oleic safflower).

because the several major saturated fatty acids have different metabolic effects. Palm oil is rich in palmitic acid and increases the total:HDL ratio considerably more than do palm kernel oil and coconut oil—which are rich in lauric and, to a lesser extent, myristic acid.⁷ Thus, judging by effects on the total:HDL ratio, palm oil is the least healthful of the three tropical oils.

- "[Palm oil] Is extracted from the palm's fruit, not the palm's kernel." In the context of a list of reasons as to why palm oil is purportedly healthful, that label statement is misleading. Just because the oil is extracted from the fruit does not make it more or less healthful than oil extracted from the kernel. Indeed, as noted above, judging by the total:HDL ratio, palm kernel oil, notwithstanding its higher content of saturated fat, is less harmful than palm oil.
- "[Palm oil] Is widely used in Europe as an alternative to partially hydrogenated oils." Among some people, being "used in Europe" may suggest that a food is healthful (perhaps because many consumers of Newman's Own products agree with Europeans who have rejected genetically engineered foods and applaud the "Precautionary Principle") and that is apparently what this label statement seeks to convey. In the context of the label's strong defense of palm oil's healthfulness, this statement may be deceptive.

That Newman's Own products are misbranded is supported by past court decisions. Statements that are technically accurate but give the wrong impression to consumers are considered misleading. See U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 442-43 (1924) ("The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false."); U.S. v. An Article of Food ... 'Manischewitz ... Diet Thins', 377 F.Supp. 746, 749 (E.D.N.Y. 1974) ("Even a technically accurate description of a food or drug's content may violate 21 U.S.C. § 343 if the description is misleading in other respects."); U.S. v. An Article of Food Labeled Nuclomin, 482 F.2d 581 (8th Cir. 1973) (finding a technically accurate label to be misleading because some of the listed ingredients were not needed in human nutrition or were included in such insignificant amounts as to be worthless).

Some companies are being encouraged by the FDA's impending labeling requirement for trans fat to switch to other oils. As we emphasized in our May 18th petition calling on the FDA to declare that partially hydrogenated oil can no longer be considered Generally Recognized As Safe and our July 22nd petition calling on the FDA to require restaurants to disclose the presence of partially hydrogenated oil and trans fat, the FDA immediately should encourage food processors and restaurants that wish to avoid using partially hydrogenated oil to switch, not to

⁷ Ibid.

palm and other tropical oils, but to more-healthful oils, such as soy, canola, corn, sunflower, and safflower oils, high-oleic or low-linolenic varieties of those oils, or to inter-esterified oils. Halting deceptive labeling claims, such as those on Newman's Own cookies and popcorn, would send a useful signal to the food industry.

Sincerely,

Michael F. Jacobson, Ph.D.

Executive Director

cc: Robert Brackett, Daniel Troy

Attachments: Newman's Own labels

Michael F. Jacobson