Christine Lewis Taylor, Ph.D.
Director of Office of Nutritional Products,
Labeling and Dietary Supplements HFS-800
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Taylor:

The Center for Science in the Public Interest (CSPI) is filing this complaint to request that the Food and Drug Administration (FDA) take enforcement action against Ben & Jerry's Homemade Holdings, Inc. for false and misleading labels on a variety of its products. These violations cause the products to be misbranded within the meaning of Section 403(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 343(a).

The cover of the container for Ben & Jerry's "everything but the . . . 2 twisted! Ice Creams" claims that the product is "All Natural" (Attachment 1). That description is false and misleading because the ingredient statement indicates that the product contains "artificial flavorings" and other man-made ingredients (cocoa processed with alkali, partially hydrogenated soybean oil, hydrogenated palm kernel oil)(Attachment 2).

In addition, more than 10 of the company's products make false and misleading "All Natural" claims. For example, Fudge Brownie Low Fat Frozen Yogurt states on the principal display panel and cover of the product that it is "All Natural" (Attachment 3). That description is false and misleading because the ingredient statement indicates that at least four ingredients are not natural: partially hydrogenated soybean oil, alkalized cocoa powder, corn syrup, and corn syrup solids (Attachment 4). Some or all of these ingredients also appear in other Ben & Jerry's products that are labeled "All Natural."

We are aware that the FDA has not officially defined the word "natural." Nevertheless,

¹ E.g., New York Super Fudge Chunk, Chubby Hubby, One Sweet Whirled, Makin' Whoopie Pie, Fudge Central with a Fudge Truffle Core, Phish Food, Chocolate Chip Cookie Dough, Karamel Sutra, from russia with buzz 2 twisted!, Vanilla Caramel Fudge.

² Because of the complexity of the issue, resource limitations, and other Agency priorities, the FDA says it has been unable to conduct a rulemaking proceeding on the meaning

the Agency has issued a number of policy statements that indicate that the FDA would not consider the use of the term "natural" to be appropriate in connection with these Ben & Jerry's products. For example, in 1989, FDA's Acting Director of Regulatory Guidance explained in a letter that the Agency has "consistently discouraged the use of such term [natural] because its meaning is ambiguous and may unjustifiably imply to consumers that foods labeled as 'natural' are inherently superior to other foods especially in nutrient content, quality and safety." In addition, the letter said that a product should not be considered natural if it contains "an added chemical that is not a constituent of the food."³

That letter was cited as a reference in 1991 and 1993 when the Agency reiterated its "natural" policy during revisions of its nutrition-claims regulations. The Agency explained that the term natural means "that nothing artificial or synthetic. . . has been included in, or has been added to, a food that would not normally be expected to be in the food." The partially hydrogenated soybean oil, hydrogenated palm kernel oil, alkalized cocoa powder, corn syrup, and corn syrup solids are, therefore, "artificial" as that term is commonly used.

According to Webster's New Collegiate Dictionary, "artificial" is defined as "humanly contrived often on a natural model: man-made." The artificial flavorings in Ben and Jerry's are synthetic. The hydrogenated soybean oil, hydrogenated palm kernel oil, alkalized cocoa powder, corn syrup and corn syrup solids are man-made.

Hydrogenated soybean oil is not a natural ingredient obtained directly from soybeans, but is created in a factory. The shortening is derived from liquid oil, which is chemically reacted with

of the term "natural." One of the questions that the Agency said it would have to consider during such a proceeding is whether "minimal processing" (as yet to be defined) is a relevant factor in determining whether a product is natural. The U.S. Department of Agriculture (USDA) adopted a definition of "natural" that prohibits such foods from being more than minimally processed. Food Safety and Inspection Service Policy Memo 055 (Nov. 22, 1982). In any event, Ben & Jerry's "All Natural" claim is barred by the Agency's policy of not permitting the term natural to be used unless "nothing artificial or synthetic. . . has been included in, or has been added to, a food that would normally not be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993), *infra*, p. 2.

³ Letter from Raymond E. Newberry, Acting Director, Division of Regulatory Guidance, FDA to Clinton K. Davies, Ph.D., Director of Quality Assurance, National Sea Products, Inc. (Sept. 29, 1988).

⁴ 58 Fed. Reg. at 2407, *citing* 56 Fed Reg. 60421, 60466 (Nov. 27, 1991) and Letter from Raymond Newberry to Clinton K. Davies, *supra* note 3

⁵ Webster's New Collegiate Dictionary 64 (1977). "Artificial" is listed as a synonym for "synthetic." *Id.* at 1183.

hydrogen to simulate milk-fat or other "hard" fat, or to serve other functions in the food. Hydrogenated palm kernel oil also is a chemically modified vegetable fat. Moreover, the implication that the Ben & Jerry's frozen yogurt may be more healthful than similar products that are not "natural" is particularly misleading where a hydrogenated ingredient is used. Hydrogenation may generate *trans* fat, which increases LDL-cholesterol in the consumer. As the National Academy of Sciences Institute of Medicine recently concluded, there is no safe level of *trans* fat, and consumers should consume as little as possible of products containing this substance while consuming a nutritionally adequate diet.⁶

Similarly, alkalized cocoa powder is not a natural ingredient obtained directly from its botanical source. Instead, the cocoa is treated with alkali. The alkali affects the color and acidity of the cocoa, giving it a darker appearance and less bitter taste.⁷ Thus, alkalized cocoa is "man-made" and is not a constituent that consumers would expect to be contained in an ice cream labeled "All Natural."

In addition, corn syrup and corn syrup solids do not occur in nature. They are created in a factory that chemically or enzymatically degrades natural corn starch. Thus, the term "natural" should not be used.

In summary, Section 403(a) of the Federal Food, Drug and Cosmetic Act bars labeling that is false or misleading in any particular. The use of an "All Natural" description on the Ben & Jerry's labels discussed herein is false. It is also particularly misleading because the manufacturer has worked hard to project a corporate image of using only the best, natural ingredients. (Ben & Jerry's boasts on its labels (Attachment 5) that it will not even use milk from cows treated with Recombinant Bovine Growth Hormone (BGH) even though the FDA has approved BGH as safe, and milk from treated cows is indistinguishable from milk from untreated cows).

Thus, for the reasons stated herein, we urge the FDA to take enforcement action pursuant to Sections 403(a), 301(a), and 303 of the Act to halt the misbranding of these products.

Sincerely,

Michael F. Jacobson, Ph.D. Executive Director

Attachments

cc: Lester Crawford

⁶ Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, *Letter Report on Dietary Reference Intakes for Trans Fatty Acids* (2002).

⁷ See http://www.vegweb.com/glossary/docs/cocoa, viewed on July 19, 2002.

Joseph Levitt John Foret