CSPI Science in the Public Interest

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TO: Jenny Butler

Company: FDA Dockets Management

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Total Number of pages INCLUDING this cover sheet: 1

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SENDER'S Phone Number: 202-332-9110, ext. 337

SUBJECT: Letter of May 13 - J.M. Smucker Co.

COMMENTS:

This is to confirm that our letter to FDA of May 13, 2003, concerning deceptive labeling by J.M. Smucker Co. was intended by us to be submitted as a comment to be included in Docket Nos. 95P-0256 and 97P-0130. Thank you for your assistance.

Bruce Silverglade

97P-0130 C170

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CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

May 13, 2003

Joe Levitt, Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Request for Regulatory Action to Prohibit Misleading Labeling Claims by The J.M Smucker Company; *See,* Petition for Proposed Rulemaking and Regulatory Action to Prohibit Misleading Food Labeling (Docket No. 95P-0256) and Petition to Require Percentage Ingredient Labeling (Docket No. 97P-0130).

Dear Mr. Levitt:

Requested Action

The Center for Science in the Public Interest (CSPI) requests that the Food and Drug Administration (FDA) take regulatory action to protect consumers from misleading ingredient claims by The J.M. Smucker Company (hereinafter "Smucker's") and to ensure that consumers are provided with complete, easy-to-read information about the ingredient content of Smucker's products.

1. The FDA Should Prohibit Misleading Ingredient Claims by Smucker's.

CSPI requests that the FDA prohibit deceptive labeling claims that misrepresent the amount of fruit in Smucker's "Simply 100% Fruit" spreadable fruit products (Att. 1). Smucker's "Simply 100% Fruit Strawberry" simply is not made only from strawberries. The product actually consists of only 30% strawberries. Similarly, Smucker's "Simply 100% Fruit Blueberry" actually consists of only 43% blueberries. Both products contain more fruit syrup than fruit (69% for the strawberries and 56% for the blueberries). Moreover, the syrups are actually made from apple and pineapple juice[1] rather than the fruit named on the front label (principal display panel).

We obtained the percentages of actual fruit content from the labels of Smucker's products sold in Thailand (Att. 2). Thailand is one of at least 18 countries around the world that require the percentages of major ingredients to be listed on the label. Company representatives confirmed to CSPI that the firm's products sold overseas are made in the U.S. and are the same as

[1] Telephone conversation between Al Yeagley, Director of Corporate Quality Assurance, J.M. Smucker Company, and Bruce Silverglade, Director of Legal Affairs, CSPI, May 6, 2003.

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those sold here.[2]

Under U.S. law, fruit preserves and jams must contain at least 47% actual fruit,[3] but there is no minimum for spreadable fruits because they are not subject to a standard of identity. Despite the name "Simply 100% Fruit," there is significantly less fruit in that product than in the company's preserves: 30% fruit in the strawberry spread and 43% in the blueberry variety.[4]

Despite its higher percentage of fruit content, the traditional preserves cost less per ounce than the company's deceptively labeled "Simply 100% Fruit." We understand that preserves made with ordinary sugar may cost less to produce than spreadable fruits made with fruit syrup. However, many consumers who are trying to increase their consumption of fruit, as recommended by health authorities,[5] are likely to believe that they can help achieve that goal by paying more for a premium product labeled "100% Fruit." Ironically, such consumers would actually be getting significantly less nutritious fruit than if they purchased a less expensive product labeled "preserves."[6]

CSPI brought similar problems to the attention of the FDA in a petition submitted to the

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[2] Telephone call between Bruce Silverglade and Al Yeagley, May 6, 2003; Telephone call between Joleen Okun, research associate, CSPI, and Smucker's consumer relations department, April 2, 2003, Reference #6108350A. In an April 8, 2003 telephone conversation, CSPI asked how much real fruit is actually contained in the company's "Simply 100% Fruit" products. Company representatives declined to answer, arguing that the information was "proprietary" even though such information is routinely disclosed on the ingredient labels of Smucker's products sold overseas.

[3] 21 C.F.R § 150.160 (d)(1).

[4] In a telephone call by CSPI to Smucker's Consumer Relations Department, a company representative claimed that "spreadable fruits" must contain less fruit than preserves in order to be "spreadable." However, competitors of Smucker's, such as Polaner, sell spreadable fruit products that contain more than the amount of fruit required in preserves; telephone call between Joleen Okun, CSPI, and Smucker's consumer relations department, April 10, 2003. At least one competitor – B & G – sells a product called Polaner's "Spreadable Apricots" that claims to contain "More Fruit Than Standard Preserves" (in this case more than 47% minimum that is required by law, *see* 21 CFR Part 150.160(d)(1)).

[5] See, Dietary Guidelines for Americans, U.S. Department of Health and Human Services and the U.S. Department of Agriculture, 2000; World Health Organization (WHO), Report on Diet, Nutrition, and the Prevention of Chronic Diseases, 2003. The WHO report identified 14 classes of foods with protective effects against chronic diseases -- fruit led the list.

[6] If Smucker's challenges this fact, or argues that the First Amendment protects the right of the company to make such claims under the commercial free speech doctrine, then the FDA should demand that the company sponsor an FDA-run consumer research study to evaluate consumer understanding of the "100% Fruit" claim.

agency on August 2, 1995 (Docket No. 95P-0256).[7] CSPI argued at that time that a J.M. Smucker Company product called "Simply Fruit - Strawberry" was misleadingly labeled because the product contained more clarified white grape juice concentrate than strawberries. While the product's ingredient list has changed, it still contains more fruit syrup made from apple and pineapple juice than strawberries. Furthermore, it is now called "100% Simply Fruit - Strawberry."

2. The FDA Should Expand Requirements for Percentage Ingredient Labeling.

Misleading claims ideally should be banned completely. However, because the FDA has failed to do that, one way to mitigate the deceptive impact of such claims is to require companies to disclose the percentages of key ingredients. Thus, the FDA should set forth the specific circumstances and manner in which the percentages of important ingredients must be disclosed on the label. Such disclosures should be required in the ingredient list and, in the case of highlighted ingredients, on the front of the package, regardless of whether the label discloses that an ingredient is included in the form of a whole food, juice, or flavorings. The type size and style of such disclosures should be expressly specified to ensure readability.

The FDA's general rules for common or usual names require that the percent of characterizing ingredients must be declared when:

> the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.[8]

The general principle encompassed in this regulation, however, has rarely been implemented by the agency and has not been embraced voluntarily by the food industry.[9]

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[7] CSPI's 1995 petition also named Polaner "All Fruit," manufactured by B & G Foods, Inc., and Sorrel Ridge "100% Fruit" manufactured by Allied Old English, Inc.

[8] 21 C.F.R. § 102.5(b).

[9] The FDA has issued four common or usual name regulations requiring that the percent of a characterizing ingredient be declared: 21 C.F.R. §§ 102.23 (peanut spreads), 102.33 (beverages that contain fruit or vegetable juice), 102.37 (mixtures of edible fat or oil and olive oil), and 102.54 (seafood cocktails). Although the agency has not implemented its general policy beyond these four foods, it stressed in 1993 that "The agency emphasizes . . . that the percentage of characterizing ingredients must be declared, as provided in § 102.5(b) . . ." 58 Fed. Reg. 2850, 2865 (Jan. 6, 1993).

3. The FDA Should Align its Policies with International Norms and Support the Development of an Expanded Percentage Ingredient Labeling Standard by the United Nations Codex Alimentarius Commission.

CSPI petitioned the FDA in 1997 to harmonize its regulations in this area with those of the European Union, which already requires percentage ingredient labeling for many major ingredients (Docket No. 97P-0130). American companies doing business in Europe comply with those regulations. Furthermore, Australia and New Zealand have finalized similar requirements for percentage ingredient labeling, and the Codex Alimentarius Commission's Committee on Food Labeling (CCFL) is reconsidering its existing international standard in this area. Thailand has maintained similar requirements for more than a decade. These facts call for a timely and proactive response by the FDA to protect American consumers by developing and enforcing policies consistent with the emerging international consensus in support of percentage ingredient labeling of important ingredients in prepackaged foods.

It is unconscionable that for years the FDA has failed to protect consumers from deceptions that have both health and economic consequences. Although we are well aware of the FDA's staffing constraints, it would be disingenuous for the FDA to attribute its lack of action to its scarcity of funds. It is noteworthy that the U.S. government delegation to the Codex Committee on Food Labeling (CCFL), which the FDA leads, has opposed expanded international standards for percentage ingredient labeling that could serve as a model for FDA action. We further note that food-industry trade associations representing multinational companies have urged the FDA not to support further work on this matter by Codex.[10] Thus, we surmise that FDA inaction in this area is not the result of limited resources, but rather the latest manifestation of the Agency's reluctance to support a measure opposed by the food industry even though the measure could improve consumer protection and further consumer health.

4. The FDA has Ample Legal Authority to Stop Misleading Labeling by Smucker's and Require Percentage Ingredient Labeling.

The FDA has the authority to take the actions requested here under sections 201(n), 403(a), 403(f), 403(i), and 701(a) of the FFDCA.[11] Section 701(a) authorizes the agency to adopt regulations for the "efficient enforcement of this Act."[12] Section 403(a) prohibits labeling that is "false or misleading in any particular."[13]

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[10] Smucker's products are distributed in 45 countries. Thus, companies like Smucker's have a great interest in the development and application of international standards developed by Codex.

[11] 21 U.S.C. §321(n), §343(a), §343(f), §343(i), and §371(a).

[12] 21 U.S.C. §371(a).

[13] 21 U.S.C. § 343(a). *See American Frozen Food Institute v. Mathews*, 413 F.Supp. 548 (D.C. Cir. 1976), *affirmed*, 555 F.2d 1059 (1977); *United States v. Vitasafe Formula*, 226

In determining whether the labeling is misleading, section 201(n) states that "representations made or suggested by statement, word, design, device, or any combination thereof" shall be taken into account, as well as the extent to which the labeling fails to reveal facts material to any such representations.[14] The percent of fruit contained (or purportedly contained) in preserves or a spread is material to the purchasing decision. Why else would Smucker's be able to command a higher price for its 100% fruit products than it can for a product that actually contains more fruit?

The FDA has relied on its misbranding and rulemaking authority to prescribe requirements for affirmative disclosures. For example, more than 50 years ago, the FDA recognized that a cookie product could only be referred to as "butter flavored," not merely "butter cookie" if shortenings other than butter were used in the product. That is because consumers likely interpreted the unqualified use of the word "butter" to mean that the only shortening ingredient in the product was butter. FDA required the cookie product to be re-labeled "Butter flavored cookies" provided the ingredient list stated the percentages of various shortenings used in the product, i.e. "6 percent butter, 94 percent other shortening."[15] More recently, the FDA required affirmative disclosures in conjunction with its nutrient claims regulations.

In addition, section 403(i) of the Act states that a food product not subject to a standard of identity will be considered misbranded unless its label includes the common or usual name of the food.[16] Without an appropriate common or usual name, a label does not adequately inform consumers of the true nature of the product.

The FDA's "common or usual name" regulations require that a food label accurately

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F.Supp. 266 (D.C.N.J. 1963), *remanded on other grounds*, 345 F.2d 846, *cert. denied*, 382 U.S. 918 (any single misleading, ambiguous or overemphasized statement or representation in labeling of a food renders it misbranded); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 42 (C.A. Mass. 1957) *cert. denied*, 354 U.S. 923 (1958) (the intent of the act is to prevent deception whether by "palpably false claims" or by "clever indirection and ambiguity in the creation of misleading impressions.")

[14] 21 U.S.C. § 321(n). The recommended "disclosure" approach for remedying many of the misleading labeling practices discussed in this document is based on this section of the FDCA, which provides that a material omission can render a label misbranded. This approach is consistent with the approach followed by the FDA in its nutrient content claim regulations, which require that certain claims be accompanied by disclosure statements in order to prevent deception. For example, a "reduced," "lower," "less," or "light" claim must be accompanied by a statement that discloses the amount of the particular nutrient in the product and in the relevant reference food. *See, e.g.*, 56 Fed. Reg. 60421, 60446 (1991); 21 C.F.R. §101.62(b)(4).

[15] Food, Drug, Cosm. Law Reports (CCH), ¶ 50,124.21 (TC-92), Feb. 21, 1940.

[16] 21 U.S.C. § 343(i).

identify or describe the basic nature of the food or its characterizing properties or ingredients.[17] FDA regulations also specify that the common or usual name of a product should include the percentage of any characterizing ingredient when this percentage has a material bearing on price, on consumer acceptance, or when the labeling creates an erroneous impression that said ingredient is present in an amount greater than is actually the case.[18] As previously mentioned, the FDA's common or usual name regulations could provide a template for action, but the agency has ignored this area.

In brief, the FDA has ample authority to take the actions requested in this petition that are necessary to protect both consumers' health and pocketbooks.

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[17] 21 C.F.R. § 102.5(a).

[18] 21 C.F.R. § 102.5(b).

Conclusion

It is essential that the FDA sides with the interests of consumers and ensures that the public's health is not undermined by label claims that imply that food products contain substantial amounts of nutritious ingredients, such as fruits, when this is not the case. The FDA should prohibit deceptive claims made by Smucker's and require that the percentages of important ingredients be disclosed.

Sincerely,

Bruce Silverglade
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Ilene Ringel Heller
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