July 26, 2001

Joe Levitt, Director Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. S.W. Room 6815 Washington, D.C. 20204

Re: Request for Enforcement Action to Prohibit Misleading Ingredient Labeling Claims (Docket No. 95P0256), Petition to Require Percentage Ingredient Labeling (Docket No. 97P0130), and Petition to Establish Format Requirements for Ingredient Lists.

Dear Mr. Levitt:

The Center for Science in the Public Interest (CSPI) requests that the Food and Drug Administration (FDA) take a series of regulatory actions to protect consumers from misleading ingredient claims and to ensure that consumers are provided with complete, easy-to-read information about ingredient content.

1. The FDA Should Prohibit Misleading Ingredient Claims

CSPI requests that the FDA prohibit misleading labeling claims that misrepresent the amount of important ingredients, such as fruits, vegetables and whole grains, that are contained in processed foods. That problem is discussed in the enclosed article "Ingredient Secrets" which was published in the July-August 2001 issue of our *Nutrition Action Healthletter* (Att. 1). For example:

! Chex "Milk 'n Cereal Bars" boast that the bars have "[t]he nutrition of a bowl of cereal with milk" and a "filling made with real milk" (Att. 2). Those claims imply that the "real milk filling" provides the nutritional value of milk. In fact, the milk filling is made mostly of sugar plus nonfat milk, lactose, palm kernel oil, partially hydrogenated soybean oil, artificial flavors and other additives. The calcium in the product is mostly added through fortification, and is not from milk as the label implies. Furthermore, each Milk 'n Cereal Bar has 13 grams of sugar while most Chex cereals in traditional form contain only two to five grams of sugar per serving. Moreover, while the traditional Wheat Chex cereal has 5 grams of fiber, the Cereal Bars have none. Parents who may view these bars as virtually equivalent to a serving of Chex cereal and milk may be misled.

- ! Stonyfield Farm's "YoSqueeze Strawberry Stratosphere" is sold in a box that is adorned with strawberries, but there are no strawberries in the product (Att. 3). The strawberry flavor is provided by natural flavoring, and the color is provided by beet juice concentrate. The front of the package contains only an inconspicuous disclosure that the product is "naturally flavored" and does not inform consumers that the product contains no strawberries. Consumers who expect to receive the nutrients, fiber, and phytochemicals that are present in real strawberries are being fooled.
- letty Crocker "Stir 'n Bake Carrot Cake Mix with Cream Cheese Frosting" contains only a minuscule amount of carrot powder despite the prominence of the term "carrot" in the product name (Att. 4). Carrot powder is the very last ingredient in the ingredient list, which lists ingredients in descending order of predominance by weight. According to the ingredient label, the product has more salt, cinnamon, powdered cellulose, Red Lake 40, xanthan gum, and sodium stearoyl lactylate than carrot powder. Many consumers, of course, would prefer carrot cake with substantial amounts of carrots which are rich in nutrients and phytochemicals. The term "artificially flavored" appears on the product label but is printed in a difficult-to-read type style and, moreover, does nothing to alert the consumer to the minuscule amount of carrots in the product. The name of the product thus misleadingly represents the amount of carrots in the food.

Additional examples of similarly deceptive labels are detailed in the enclosed article.

Currently, the FDA's flavor labeling rules, 21 C.F.R. § 101.22(i)(l), permit a manufacturer to market products like strawberry shortcake that contains no strawberries, so long as the label includes the word "flavor" in close proximity to the name of the characterizing ingredient. But many consumers (even if they notice such disclosures, which are often printed in a difficult-to-read type style) are not aware that the use of the term "flavor" means that only minuscule amounts of strawberries, or perhaps none at all, are present in the product. Many consumers instead may believe that a flavoring has been added to enhance a product's taste rather than to substitute for the absence of a key ingredient. That misrepresentation is often reinforced by label depictions of fruit (or other important ingredients) that are not actually contained in the product, except in the form of natural or artificial flavorings.

Illustrations of such ingredients should not be permitted unless significant amounts are actually present in the product. Furthermore, terms like "naturally and artificially flavored" should be made part of, and printed in the same size and type style as the product's name, rather than displayed, as is currently the practice, in the form of difficult-to-read disclaimers.

CSPI brought such problems to the attention of the FDA almost six years ago in a petition submitted to the agency on August 2, 1995 (Docket No. 95P0256). Although many years have elapsed since the filing of that petition, the overwhelming majority of the products cited in it (that are still available in the Washington, D.C. market) continue to be marketed with the same or similarly misleading claims. In brief, manufacturers continue to misleadingly represent the

ingredient contents of their products, emphasizing the more healthful, costly ingredients far out of proportion to their actual presence in the foods. Those claims imply that such products are rich in such ingredients whereas they actually contain only small amounts or sometimes none at all. A chart comparing current labeling claims and ingredients to those in use at the time of our petition is enclosed (Att. 5).

2. The FDA Should Expand Requirements for Percentage Ingredient Labeling

In addition to taking action against the most egregiously deceptive claims, the FDA should adopt a regulation setting forth the specific circumstances and manner in which the percentage 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 a product in the form of added flavoring. The type size and style of such disclosures should be expressly specified to ensure readability.

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.¹

The general principle encompassed in this regulation, however, has rarely been implemented by the agency and has not been embraced by the food industry.²

Therefore, the agency should expressly require by regulation that ingredient labels include percent ingredient declarations for all important ingredients and that the percentage of highlighted ingredients appear on the front of food packages. Those percent declarations should be required even if the label discloses that the product contains added flavorings. If the product contains none of an ingredient that consumers would expect to be contained in a product, the front label should

¹ 21 C.F.R. § 102.5(b).

² 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).

state "Contains no [name of ingredient]." Such requirements are especially crucial in light of the FDA's continuing failure to ban deceptive misrepresentations that appear on labels.

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. 97P0130). 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 has undertaken new work to develop an international standard for this area. Those developing and enforcing policies consistent with the emerging international consensus in support of percentage ingredient labeling of important ingredients in pre-packaged foods.

3. The FDA Should Establish Specific Format Requirements for Ingredient Lists

Currently, many food products bear ingredient lists that appear to be designed to be difficult to read. The FDA should, therefore, issue specific format regulations for ingredient lists that ensure that such lists are easily readable. We are submitting under separate cover a new petition to the agency that requests that the FDA issue a regulation establishing a minimum type size and other format standards for ingredient lists that would make them easier to read. Those steps are especially necessary not just to prevent the public from being defrauded, but also to assist consumers who rely on labels to avoid serious, sometimes life-threatening, allergic reactions, food intolerances, or sensitivities to particular ingredients. Such steps are also necessary to assist consumers seeking to avoid added sugars or other ingredients of low nutritional value.

4. Conclusion

It is unconscionable that for years the FDA has failed to protect consumers from deceptions that have both health and economic consequences. We recognize the FDA's staffing constraints, but it is essential that the agency ensure that consumers are not misled and that the public health is not undermined by labels that imply that food products contain substantial amounts of nutritious ingredients such as whole grains, fruits, and vegetables, when that is not the case. The FDA should prohibit deceptive claims, require that the percent of important ingredients be disclosed, and issue new format rules ensuring that ingredient lists are easily readable.

The FDA has clear authority to take the actions we request under sections 201(n), 403, and 701 of the Federal Food Drug and Cosmetic Act,³ which empower the agency to prohibit

³ 21 U.S.C. §§ 321(n), 343 and 371.

misleading labeling. The FDA should act without further delay. We look forward to working with the agency in this regard.

Sincerely,

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