

March 14, 2006

Dr. Barbara Schneeman, Director  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20852-2367

Dear Dr. Schneeman:

**I. Introduction**

The Center for Science in the Public Interest (CSPI) urges you to take prompt action to halt misleading trans-fat claims on foods that contain significant levels of saturated fat. Those claims mislead consumers because such products, notwithstanding the low level or absence of trans fat, still increase the risk of heart disease. Such products are misbranded under sections 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (FDCA).

**II. Numerous Products that Contain Saturated Fat Make Misleading Claims Concerning Trans Fat Content**

On July 11, 2003, the Food and Drug Administration (FDA) withdrew sections of a proposed rule concerning the definition of nutrient content claims for trans fat. 68 Fed. Reg. 41434 (July 11, 2003). Simultaneously, FDA issued an Advance Notice of Proposed Rulemaking (ANPR) soliciting information and data that could be used to establish new nutrient content claims about trans fat. In that notice, FDA indicated that it would consider exercising its enforcement discretion and permit such claims "if a company wants to make a statement about the fat content of a product that is demonstrably true, *balanced, adequately substantiated, and not misleading.*" 68 Fed. Reg. at 41509 (emphasis added).

In the aftermath of the decision to withdraw the proposed nutrient content claim rules for *trans* fat, numerous misleading labels have appeared: For example:

- **Mrs. Smith's Apple Pie:** A prominent red banner over the brand name states "0g trans fat per serving." The product contains 7 grams of saturated fat per serving. (Attachment A)

- **Nestle Crunch Ice Cream Bars:** A banner over the large-print word “Crunch” states that there is “0g trans fat!” The product contains 11 grams of saturated fat per serving. (Attachment B)
- **Sara Lee Pumpkin Pie:** The label states that the product has “zero 0g transfat.” (Attachment C)
- **Mrs. Paul’s Crunchy Fish Fillets:** A banner stating “0 grams trans fat per serving” appears directly above the brand name. The product contains 5 grams of saturated fat per serving. (Attachment D)
- **Spectrum: Organic All Vegetable Shortening:** A yellow highlighted banner stating “0 grams trans fat” appears on the front label. The product contains 6 grams of saturated fat per serving. (Attachment E)

The Daily Value for saturated fat is 20 grams. 21 C.F.R. § 101.9(c)(9). Thus, a product -- like all those noted above -- with 4g or more is considered “high” in saturated fat. 21 C.F.R. § 101.54(b), 21 C.F.R. § 101.13(h), 21 C.F.R. § 101.14(e)(3). The Nestle Crunch Ice Cream Bars provide 55 percent of the Daily Value in a 62 gram bar!

Some manufacturers are misleadingly publicizing the absence of trans fat to convince consumers that their products are healthful. However, “0g trans fat” claims on products that contain excessive amounts of saturated fat mislead consumers by implying that the food does not raise serum cholesterol levels or the risk of heart disease. In fact, though, high levels of saturated fat in those foods do promote heart disease. Permitting manufacturers to continue such labeling practices defrauds consumers.

Given that the FDA has withdrawn its original proposal and indicated that it would permit nutrient content claims for trans fat only if they were not misleading, CSPI urges the Agency to halt the deceptive claims described above and any similar ones.

### **III. Congress Empowered the Agency to Ban Certain Nutrition Claims that are Misleading**

Congress gave FDA explicit authority to prohibit claims where “the claim is misleading in light of the level of another nutrient in the food.” FDCA § 403(r)(2)(A)(vi). FDA has used this authority to limit “saturated fat free” claims to products that contain less than 0.5 grams of saturated fat and 0.5 grams of *trans* fatty acids. 21 C.F.R. § 101.62(c)(1). The Agency explained that:

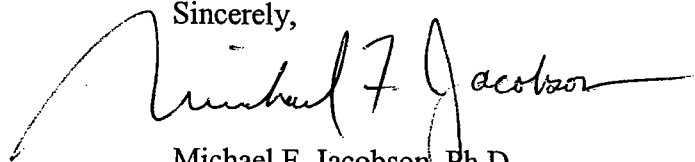
It would be misleading for products that were labeled ‘saturated fat free’ to contain measurable amounts of *trans* fatty acid because consumers would expect such products to be “free” of components that significantly raise serum cholesterol.

58 Fed. Reg. 44020, 44027 (Aug. 18, 1993).

Similarly, consumers expect that a product labeled "no trans fat" is free of saturated fat.

Although FDA had initially proposed a 0.5 gram saturated fat limit for "trans fat free" claims, that proposal was withdrawn because the FDA claimed that there was "insufficient scientific information at this point in time to support a decision on appropriate definitions" for claims relating to trans fat. 68 Fed. Reg. 42434, 41464 (July 11, 2003). CSPI disagrees with that conclusion, especially given the new guidance regarding trans fat intake provided by the 2005 Dietary Guidelines Advisory Committee for the Dietary Guidelines for Americans and the FDA Food Advisory Committee's opinion that on a gram-for-gram basis trans fat is more harmful than saturated fat.<sup>1</sup> There is no scientific uncertainty that the amounts of saturated fat in the products discussed above are unhealthful, that the labeling is deceptive, and that the "0 trans fat" claims for such products should be halted.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael F. Jacobson", with a long horizontal flourish extending to the right.

Michael F. Jacobson, Ph.D  
Executive Director

Enclosures

cc:

Felicia Billingsly  
Margaret Glavin  
Directors of Regional Offices

---

<sup>1</sup> Nutrition Subcommittee of the Food Advisory Committee, Center for Food Safety and Applied Nutrition, Summary Minutes April 27 & 28, 2004.

PROOF OF PURCHASE

Dear Consumer: We at Schwan's Bakery, Inc. take pride in the quality of our products and we welcome your questions or comments. When writing us, please be sure to include the name of the product and the purchase panel with your letter to: Schwan's Bakery, Inc., Consumer Affairs Department, 29520 Camino del Rio East, Suite 200, San Diego, CA 92108. Contact our website at [www.schwansbakery.com](http://www.schwansbakery.com), or call us at 877-RLHG-PIN (877-756-4746).

**0g TRANS FAT** PER SERVING  
& **FLAKIER CRUST!**\*

# Mrs. Smith's®

## TRADITIONAL RECIPES

Bake it  
fresh!

# Apple Pie

BEFORE SERVING

NET WT 37 OZ (2 LBS 5 OZ) 1.05kg

SERVING SIZE

KEEP FROZEN

Attachment A

**0g TRANS FAT!** PER SERVING

# Mrs. Smith's

# Apple Pie





Attachment B

# **Nutrition Facts**

Serving Size  
1 Bar (62g)  
Servings Per  
Container: 8  
**Calories 220**  
Calories from Fat 130

Amount Per Serving % Daily Value\*

**Total Fat 15g 23%**

**Saturated Fat 11g 57%**

**Trans Fat 0g**

**Cholesterol 15mg 6%**

**Sodium 55mg 2%**

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 0%

Amount Per Serving % Daily Value\*

**Total Carb 18g 6%**

**Dietary Fiber 0g 0%**

**Sugars 15g**

**Protein 2g**

\* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total fat	Less than	65g	80g
Sat fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

**INGREDIENTS:** MILKFAT AND NONFAT MILK, COATING (COCONUT OIL, SUGAR, PALM OIL, CHOCOLATE, REDUCED MINERALS WHEY, MILK, SOY LECITHIN, ARTIFICIAL VANILLA FLAVOR), SUGAR, CORN SYRUP, CRISPED RICE (RICE FLOUR, MALT EXTRACT, SUGAR, SALT), WHEY

**POWDER, STABILIZER (MONO- DIGLYCERIDES, GUAR GUM, CALCIUM SULFATE, CELLULOSE GUM, CARRAGEENAN), NATURAL AND ARTIFICIAL FLAVOR, ANNATTO COLOR.**

**ALLERGY INFORMATION: MANUFACTURED ON SHARED EQUIPMENT WITH PRODUCTS THAT CONTAIN PEANUT INGREDIENTS.**

**DISTRIBUTED BY: DREYER'S GRAND ICE CREAM, INC.**  
5829 COLLEGE AVENUE, OAKLAND, CA 94618-1391  
TRADEMARKS REPRODUCED UNDER LICENSE.  
Visit us at [www.Icecream.com](http://www.Icecream.com)

**KEEP FROZEN UNTIL SERVED.**  
**INNER UNITS NOT LABELED FOR RETAIL SALE.**

**QUALITY GUARANTEE:**  
If you are not completely satisfied with this product, please contact us with the reason, the UPC Bar Code, and the code numbers from the side panel of this carton. We will gladly replace your purchase.



**BEST BY 10/20/06**  
**24-52-03BB-1236**

Attachment B

# Sara Lee®

ZERO  TRANS FAT  
SAME GREAT TASTE



PUMPKIN PIE

1  
D  
P FROZEN

Attachment C



**IMPORTANT:**

STORE IN  
FREEZER UNTIL  
READY TO BAKE

MICROWAVING NOT  
RECOMMENDED

**Nutrition Facts**

Serving Size 1/8 pie (131g)  
Servings Per Container 8

Amount Per Serving

**Calories 260**

Calories from Fat 90

	% Daily Value*
<b>Total Fat</b> 10g	<b>15%</b>
<b>Saturated Fat</b> 4g	<b>20%</b>
<b>Trans Fat</b> 0g	

**Cholesterol** 40mg **13%**

**Sodium** 320mg **13%**

**Total Carbohydrate** 39g **13%**

**Dietary Fiber** 2g **7%**

**Sugars** 20g

**Protein** 4g

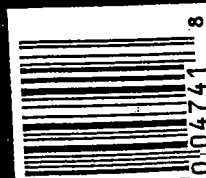
**Vitamin A** 50% • **Vitamin C** 0%

**Calcium** 6% • **Iron** 8%

\*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
<b>Total Fat</b>	Less than	65g	80g
<b>Sat Fat</b>	Less than	20g	25g
<b>Cholesterol</b>	Less than	300mg	300mg
<b>Sodium</b>	Less than	2,400mg	2,400mg
<b>Total Carbohydrate</b>		300g	375g
<b>Dietary Fiber</b>		25g	30g

Calories per gram:  
Fat 9 • Carbohydrate 4 • Protein 4



Attachment C

0 Grams  
Trans Fat  
Per Serving

# Mrs. Paul's®

## 10 Crunchy Fish Fillets

*Golden, Delicious Breading*

**New!** SEALED IN  
Flavor Lock  
Pouch

KEEP FROZEN 

NET WT 18.7 OZ (1LB 2.7 OZ) 530g

Serving Suggestion

Attachment D

*Mrs. Paul's*

## Nutrition Facts

Serving Size 2 Fillets (106g)  
Servings Per Container 5

### Amount Per Serving

Calories 250 Calories from Fat 120

% Daily Value\*

Total Fat 14g 21%  
Saturated Fat 5g 24%  
Trans Fat 0g

Cholesterol 25mg 8%

Sodium 470mg 20%

Total Carbohydrate 19g 6%

Dietary Fiber less than 1g 4%

Sugars 3g

Protein 9g

Vitamin A 0% • Vitamin C 0%

Calcium 2% • Iron 2%

\*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

INGREDIENTS: ALASKA POLLOCK (FISH, SODIUM TRIPOLYPHOSPHATE TO RETAIN FISH MOISTURE), BREAD CRUMBS (WHEAT FLOUR, SUGAR, SALT, YEAST), VEGETABLE OIL WITH TBHQ AND CITRIC ACID AS PRESERVATIVES (COTTONSEED OIL, AND/OR CANOLA OIL, AND/OR SUNFLOWER OIL, AND/OR SOYBEAN OIL), WHEAT FLOUR, WATER, CONTAINS 2% OR LESS OF FLOUR PRELUST (WHEAT FLOUR, ENRICHED WITH NIACIN, FERROUS SULFATE, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), SALT, SOYBEAN OIL, MODIFIED FOOD STARCH, SALT, SUGAR, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE, MONOCALCIUM PHOSPHATE), DEXTROSE, MONOSODIUM GLUTAMATE, GARLIC POWDER, ONION POWDER, SPICE, PAPRIKA.

CONTAINS FISH (POLLOCK), WHEAT.

DISTRIBUTED BY:  
PINNACLE FOODS CORPORATION  
CHERRY HILL, NJ 08002-4112 USA

Attachment D



Attachment E

## Nutrition Facts

Serving Size 1 Tbsp (13g)

### Amount per Serving

Calories 110

Calories from Fat 110

### % Daily Value\*

Total Fat 13g 20%

Saturated Fat 6g 32%

Trans Fat 0g

Cholesterol 0mg 0%

Polyunsaturated Fat 2g †

Monounsaturated Fat 5g †

Sodium 0mg 0%

Potassium 0mg 0%

Total Carbohydrates 0g 0%

Fiber 0g 0%

Sugars 0g

Protein 0g

Vitamin A 0%

Vitamin C 0%

Calcium 0%

Iron 0%

\* Percent Daily Values are based on a 2,000-calorie diet.

† Daily Value not established.

Attachment E