CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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October 27, 2005

Dr. Andrew von Eschenbach
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

We are greatly concerned about the precipitous decline in FDA's enforcement of laws and regulations prohibiting misleading food labeling. Report language accompanying both the House and Senate Appropriations bills for Fiscal Year 2006 calls on the Agency to report to Congress by February 1, 2006, on the "types of labeling violations discovered and actions taken in response to such violations."[1]

On August 18, 2005, we met with Dr. Barbara Schneeman, Director of FDA's Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), and members of her staff to discuss the Agency's enforcement policies regarding food products bearing misleading labeling. We presented Dr. Schneeman and her staff with numerous examples of the types of misleading labeling that are flooding supermarkets (Attachment A) and copies of previous CSPI complaints and petitions to which the Agency has not responded (Attachments B and C).

Based on our discussions with ONPLDS, ONPLDS does not appear to have the ability (or possibly even desire) to address the specific problems identified by Congress and CSPI. Those include misleading claims, such as "heart healthy" or "low calorie," and the inaccurate disclosure of calorie, fat, and sugar content on the Nutrition Facts Panel.

Based on our meeting, it appears that the Agency only reviews food labels during its inspections of a manufacturer's facilities, during which label violations are not a central focus. Our review of the small number of warning letters issued by the Agency shows that when inspectors examine a label, in most cases they merely identify *per se* violations of FDA regulations, such as the complete absence of nutrition information or the failure to list the name and address of the manufacturer. FDA officials told us that ONPLDS does not plan to make any systematic effort to identify and remedy the types of misleading labeling that Congress and CSPI are concerned about.[2]

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[1] S. Rep. No.109-92, at 153 (2005); H.R. Rep. No. 109-102, at 83 (2005).

[2] Although a Consumer Products Complaint System has been established by the Office of Regulatory Affairs to help identify current problems and long-term needs, deceptive labeling appears to be of only minor concern. Non-injury/illness consumer complaints "do not require immediate or prompt follow-up but may be investigated, referred, deferred to a pending EIR [Establishment

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[redacted]

1995P-0246

The attached summary of CSPI's Pending Complaint Letters to ONPLDS Regarding Labeling Violations (Attachment B) illustrates the fact that FDA has repeatedly failed to stop misleading labeling even when the labels blatantly violate the law and when the labels are sent to the FDA. CSPI is not alone in this regard; we have been contacted by manufacturers who lament that their complaints to FDA about dishonest competitors are also routinely ignored. For example:

- **Betty Crocker Super Moist Carrot Cake Mix** – The package depicts a slice of cake with visible chunks of carrots, but the product only contains minuscule amounts of carrot powder. (The chunks are composed of a variety of additives.)

- **Smucker's Simply 100% Fruit Spreadable Fruit** – The "100%" strawberry variety actually contains 30% strawberries. The "100%" blueberry variety contains only 43% blueberries. Both products contain more fruit syrup than fruit.

- **Yoplait Light Fat Free Yogurt** – claims to "burn more fat" and help dieters lose weight if they consume three servings of milk, cheese or yogurt daily. However, the U.S. government's own Dietary Guidelines Advisory Committee called the evidence on dairy products and weight loss "inconclusive."

- **Gerber Graduates for Toddlers Fruit Juice Snacks** – The package is decorated with pictures of oranges, cherries, and strawberries, but the product contains primarily corn syrup, sugar, and white grape juice. Red cabbage extract and elderberry juice concentrate are added solely for color.

FDA's *Enforcement Story for Fiscal Year 2004* indicates that since 2000, the number of seizures, injunctions and prosecutions involving the Center for Food Safety and Applied Nutrition, of which ONPLDS is a part, has declined by more than 50%, from 28 to 11. By comparison, in 1994 alone, CFSAN brought 65 enforcement actions. Moreover, FDA has not brought a single criminal prosecution involving food labeling in recent years.

We also learned at our August 18th meeting that only the equivalent of four full-time staff members at FDA headquarters and four in the field are devoted to enforcing the laws and regulations prohibiting misleading food labeling. That low staffing level is shocking given that the public assumes that the FDA is policing the labeling of more than $500 billion worth of food sold each year and that the agency has more than 9,000 full-time employees overall. Moreover, we were informed that the few FDA staff that work in the area at headquarters typically spend their time answering questions from inspectors in the field, food companies, and members of Congress, rather than developing and initiating a broader enforcement strategy to combat misleading labeling. Furthermore, inspections in

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Inspection Report], or closed without further investigation at management's discretion." FDA, ORA Field Management Directive 119, *Consumer Products Complaint System* (Rev. Jan. 12, 1994), *available at* www.fda.gov/ora/inspect_ref/fmd/fdm119.htm (visited Aug. 30, 2005). Violations of the Nutrition Labeling and Education Act are not even listed as the type of complaint that should be entered into the system.

the field are carried out only as part of a routine safety inspection of an establishment,[3] which occurs on average only every five years. Such inspections do not represent a strategic effort to stop misleading claims.

At a time when obesity and diet-related diseases have become a major health concern, honest labeling is an essential tool that consumers need to improve their diets and their health and to protect themselves from economic fraud—and that honest companies need in order to be competitive in the marketplace. We urge you to conduct a prompt review of ONPLDS' responsibilities, resources, and capabilities and then direct staff to develop and implement a comprehensive strategic plan (separate from routine establishment inspections) to restore the integrity of the food label. FDA should also seek from Congress a budget increase of $30 million over three years to create an effective labeling-watchdog unit that would address long-term concerns through rulemaking and other industry-wide policy initiatives. As it is, FDA's efforts are woefully inadequate and an insult to consumers and honest competitors.

Sincerely,

Michael F. Jacobson, PhD
Executive Director

Bruce Silverglade
Director of Legal Affairs

Ilene Ringel Heller
Senior Staff Attorney

Attachments

[3] FDA, Food Compliance Program, *Domestic NLEA, Nutrient Sample Analysis, and General Food Labeling Program* 6-7 (Nov. 30, 2000).

Attachment 1

Allergy Note: This product contains wheat and milk ingredients.

You will need:


1 Cup Water


1/2 Cup Vegetable Oil


3 Eggs*

1 **Heat** oven to 350°F (any type pan). **Grease bottom only** of 13"x9" pan or bottom and sides of all other pans (use paper baking cups for cupcakes).

2 **Beat** cake mix, water, oil and eggs in large bowl on **low speed 30 seconds,** then on **medium speed 2 minutes,** scraping bowl occasionally. **Pour** into pan.

3 **Bake** as directed below or until **toothpick** inserted in center comes out clean. Cool 10 minutes before removing from pan. Cool completely before frosting.

Pan Size	13"x9"	Two 8" Rounds	Two 9" Rounds	24 Cupcakes (2/3 full)	Bundt®
*Bake Time (in minutes)***	27-33	25-30	22-27	15-20	30-35

**Decrease bake time by 2-3 minutes if using dark or nonstick pan.

HIGH ALTITUDE (3500-6500 ft): Heat oven to 375°F. Do not use 8" rounds. Make batter using 1 1/4 cups water, 1/3 cup flour, 1/3 cup oil and 3 eggs. Beat on low speed 30 sec; beat on medium speed 3 min. Bake time (in minutes): 13"x9" 32-37, 9" rounds 25-30, Bundt 33-38. For cupcakes, use paper baking cups. Bake 15-20. Makes 30 cupcakes.

***NO-CHOLESTEROL RECIPE:** Make batter using 1 cup water, 1/4 cup vegetable oil and 3/4 cup fat-free cholesterol-free egg product or 5 egg whites. *As prepared, one serving provides 260 calories (70 calories from fat), 8 g fat (2 g saturated, 1 g trans, 2 g polyunsaturated, 2.5 g monounsaturated) and 0 mg cholesterol.*

Betty Crocker

Ultimate Carrot Cake

1 package Betty Crocker® SuperMoist® carrot cake mix
1/2 cup water
1/2 cup vegetable oil
4 eggs
1 can (8 oz) crushed pineapple in juice, undrained
1/2 cup chopped nuts
1/2 cup shredded coconut
1/2 cup raisins
1 tub Betty Crocker® Rich & Creamy cream cheese frosting

Heat oven to 350°F. Grease bottoms only of two 8" or 9" round pans; lightly flour. Beat cake mix, water, oil, eggs and pineapple (with juice) in large bowl on low speed 30 seconds; beat on medium speed 2 minutes. Stir in nuts, coconut and raisins. Pour into pans.

Bake 8" rounds 40 to 45 minutes, 9" rounds 28 to 32 minutes, or until toothpick inserted in center comes out clean. Cool 10 minutes. Run knife around sides of pans to loosen cakes; remove from pans to wire rack. Cool completely, about 1 hour. Fill layers and frost side and top of cake with frosting. Store covered in refrigerator.

HIGH ALTITUDE (3500-6500 ft): Do not use 8" rounds. Heat oven to 375°F. Add 1/3 cup all-purpose flour to dry cake mix. Decrease oil to 1/3 cup.

Visit BettyCrocker.com for more great ideas.

SuperMoist® Carrot

Introducing...

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Try All 4 Delicious Flavors!

- *Old-Fashioned Apple Crisp*
- *Southern Style Peach Cobbler*
- *Classic Cherry Cobbler*
- *Triple Chocolate Hot Fudge Cake*

The delicious cake pictured on the front of this box is frosted with Betty Crocker® Rich & Creamy cream cheese frosting.

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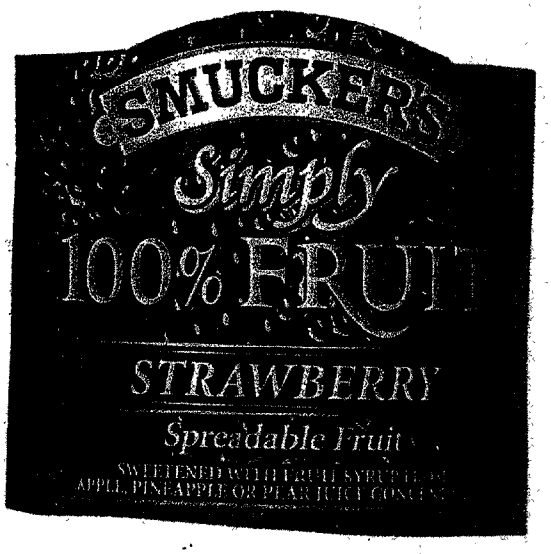
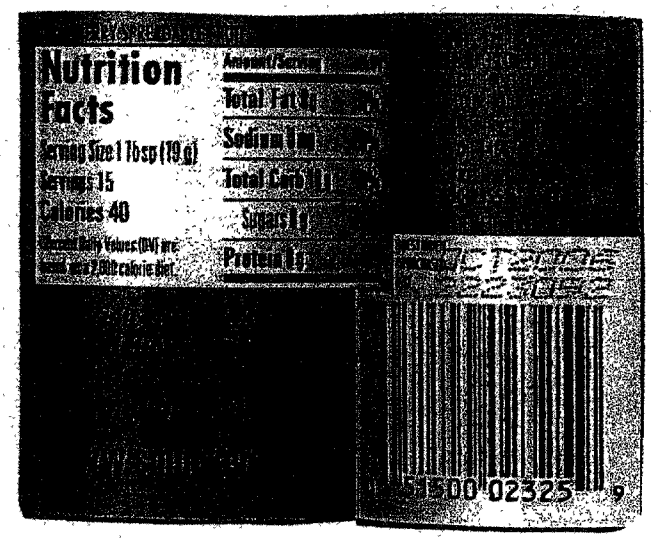
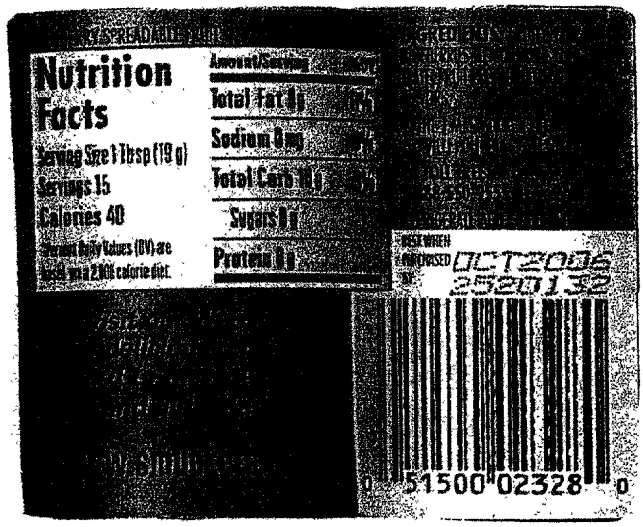


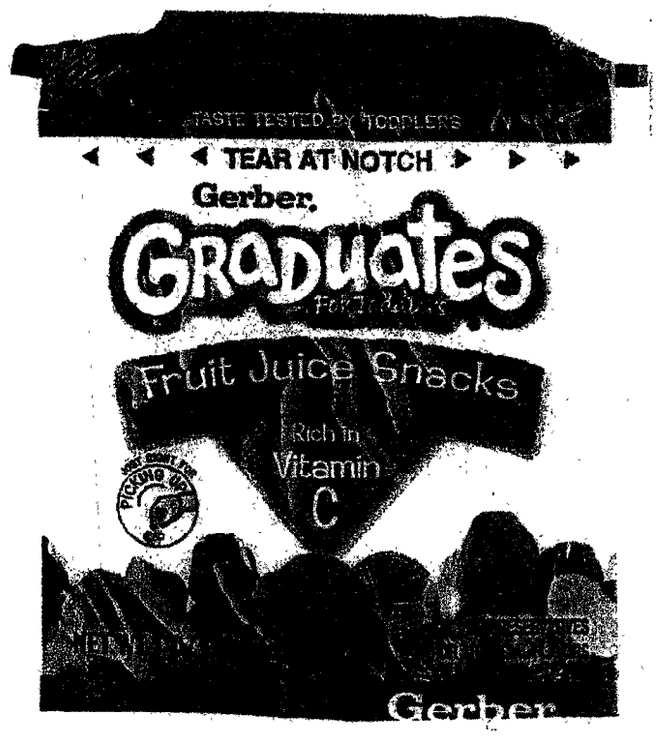


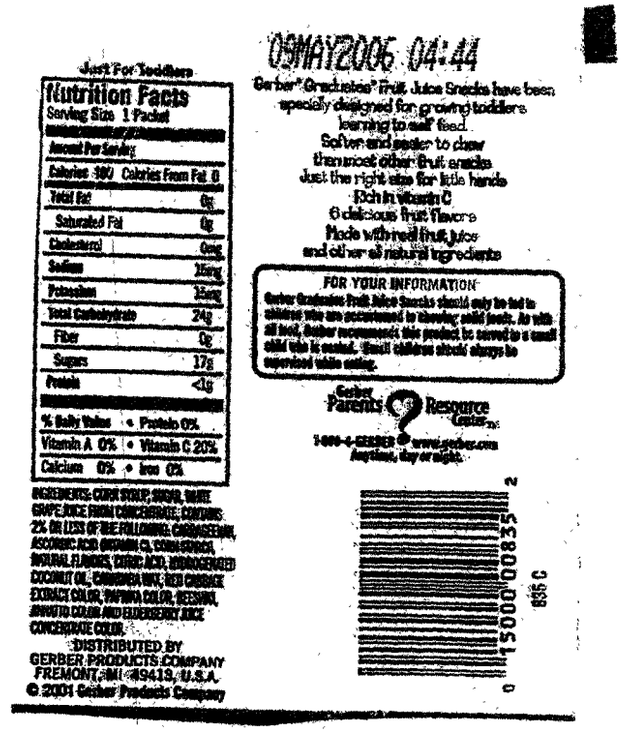
Attachment 2(a)



Attachment 2(b)

Attachment 3





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Just For Toddlers

Nutrition Facts
Serving Size 1 Packet

Amount Per Serving	
Calories 100	Calories From Fat 0
Total Fat	0g
Saturated Fat	0g
Cholesterol	0mg
Sodium	15mg
Potassium	15mg
Total Carbohydrate	24g
Fiber	0g
Sugars	17g
Protein	<1g
% Daily Value • Protein 0%	
Vitamin A 0% • Vitamin C 20%	
Calcium 0% • Iron 0%	

INGREDIENTS: CORN SYRUP, SUGAR, WHITE GRAPE JUICE FROM CONCENTRATE, CONTAINS 2% OR LESS OF THE FOLLOWING: CARRAGEENAN, ASCORBIC ACID (VITAMIN C), CORN STARCH, NATURAL FLAVORS, CITRIC ACID, HYDROGENATED COCONUT OIL, CARNAUBA WAX, RED CABBAGE EXTRACT COLOR, PAPRIKA COLOR, RESHAN, ANNATTO COLOR AND ELDERBERRY JUICE CONCENTRATE COLOR.

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Gerber® Graduates® Fruit Juice Snacks have been specially designed for growing toddlers learning to self feed.
Softer and easier to chew than most other fruit snacks
Just the right size for little hands
Rich in Vitamin C
6 delicious fruit flavors
Made with real fruit juice and other all natural ingredients

FOR YOUR INFORMATION
Gerber Graduates Fruit Juice Snacks should only be fed to children who are accustomed to chewing solid foods. As with all food, Gerber recommends this product be served to a small child who is seated. Small children should always be supervised while eating.

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Anytime, day or night.

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