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May 22, 2003

Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Citizen Petition Regarding Trans Fat Labeling
Pertaining to Docket No. 94P-0036

Dear Sir or Madam:

BanTransFat.com, Inc. hereby submits an original and three copies of the enclosed "Citizen Petition Regarding Trans Fat Labeling."

Sincerely,



Stephen L. Joseph

SLJ/sel

enclosures

94P-0036

CP 2

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CITIZEN PETITION REGARDING TRANS FAT LABELING (Pertaining to Docket No. 94P-0036)

This Petition is submitted under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Nutrition Labeling and Education Act of 1990, and any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs to regulate the labeling of food products and the protection of consumers from misleading claims and advertising by food manufacturers and vendors.

This Petition is filed in response to the FDA's current proposal to delay any trans fat labeling on food products until 2006, and its abandonment of its own previous proposal that labels state that intake of trans fat should be as low as possible.

Petitioner requests that this Petition be considered on an expedited basis. The FDA has estimated that between 2,000 and 5,600 lives a year would be saved by trans fat labeling, and 7,600 to 17,100 cases of coronary heart disease per year would be prevented. Further delaying trans fat labeling will cost lives.

THE PETITIONER

Petitioner is BanTransFat.com, Inc., a non-profit corporation organized under the laws of the State of California.

On May 1, 2003, Petitioner filed a lawsuit against Kraft Foods North America, Inc. seeking an injunction against the sale and marketing of Oreo cookies to children in California. One of the factual and legal bases for the lawsuit was that the cookies contain trans fat which is not shown on the Nutrition Facts panel on the packaging. Petitioner has voluntarily dismissed the lawsuit.

There was enormous national publicity during the week of May 12, 2003 regarding the trans fat issue and the lawsuit. Tens of millions of people who were previously unaware of the presence and danger of trans fat in their food products suddenly became aware, and word is continuing to spread. Over 100,000 people have visited Petitioner's trans fat information website since May 12, 2003. (www.bantransfats.com)

The thousands of e-mails that Petitioner has received show that the American people, particularly women, are deeply concerned and angry about trans fat and the lack of labeling. A selection of the e-mail is posted at Petitioner's website which we urge the FDA to review. (www.bantransfats.com)

On May 14, 2003, a poll was conducted by America Online. 655,296 people voted. 26% responded that "something needs to be done" about the trans fat problem identified by Petitioner in its lawsuit against Kraft. This is a very substantial percentage. We believe that if a poll were taken of women only, the percentage would be much higher. This is important, because the reality is that women are more likely than men to be the food purchasers for families.

ACTION REQUESTED

Petitioner hereby requests that the FDA:

1. Require, with immediate effect, that all food labels indicate the amount of trans fat on a separate line on the Nutrition Facts panel.
2. Require, with immediate effect, that all food labels state on the Nutrition Facts panel that "intake of trans fat should be as low as possible."
3. Require that all food manufacturers disclose on the Internet using the Nutrition Facts panel format, and via a toll free telephone number, the amount of trans fat in each of their products, accompanied by a statement that "intake of trans fat should be as low as possible." Food manufacturers would be required to implement this requirement as soon as possible, and no later than July 1, 2003.

Products already in the "pipeline" would be exempt from the requirements of paragraphs 1 and 2 above.

STATEMENT OF GROUNDS

On November 17, 1999, the FDA proposed to amend its regulations to include the trans fat content of food products on the Nutrition Facts label. (64 FR 62746) Three years then passed during which no new regulation was issued regarding trans fat labeling.

On November 15, 2002, the FDA proposed to amend its regulations to require a mandatory declaration of trans fat content on a separate line within the Nutrition Facts panel with a footnote which would read as follows: "Intake of trans fat should be as low as possible." (67 FR 69191)

In the 2002 notice, the FDA took the position that "information on the trans fat content of foods needs to be available on food labels." The FDA also pointed out in the notice that Section 2(b) of the Nutrition Labeling and Education Act of 1990 states that the Secretary of Health and Human Services, and by delegation the FDA, "shall" require that the declaration of nutrients "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."

In response to the notice, comments were submitted to the FDA, including an objection by Kraft Foods North America, Inc. Kraft argued that the statement in the proposed footnote would be "likely to mislead consumers and may result in food choices inconsistent with public health goals" and that such information would be "best left to an off-label education program."

Petitioner believes that Kraft's grounds of objection and others submitted by the food industry are completely bogus and designed to prevent them from losing market share to competitors who offer trans fat-free products.

The present omission of trans fat from the Nutrition Facts panel on food packaging is fraudulent and unconscionable. The lack of any present regulation on trans fat labeling constitutes a clear failure by the FDA to perform its legal obligation under Section 2(b) of the Nutrition Labeling and Education Act of 1990.

Petitioner understands that the FDA is proposing to delay any trans fat labeling on food products until 2006 in order to protect the interests of "small business." However, the proposed delay is not mentioned in the notice of November 15, 2002. The notice envisaged implementation after a thirty-day comment period and a reasonable period of review by the FDA. Petitioner hereby objects to the proposed delay to 2006. It is unfair and violative of applicable laws and procedures for the FDA to delay implementation by 2½ years without having invited public comments regarding such a delay in the notice. Moreover, changing a label can be accomplished easily and quickly. Companies change their packaging all the time to promote their products. It certainly does not take them 2½ years.

The FDA has estimated that between 2,000 and 5,600 lives a year would be saved by trans fat labeling, and 7,600 to 17,100 cases of coronary heart disease per year would be prevented. A delay of a further 2½ years means 5,000 to 14,000 lives lost and 19,000 to 42,750 cases of coronary heart disease, all for the sake of protecting "small business."

It is the FDA's statutory obligation to protect small children, not small business.

If we take into account the full six years from the first notice in November 1999 to 2006, that represents 45,600 to 102,600 cases of coronary heart disease and 12,000 to 30,000 lives lost because of non-labeling of trans fats. These are not statistics. They are tragedies.

Petitioner also understands that the FDA intends to abandon its proposal that labels state that intake of trans fat should be as low as possible, and that there will be no daily value shown for trans fat. Instead, the "% Daily Value" for trans fat would be left blank. The FDA appears to have caved on this issue in response to pressure from the food industry.

If a percentage daily value is shown for saturated fat, but there is a blank space for the percentage daily value for trans fat, consumers will believe that they can safely eat trans fat without limitation, and that they only need to limit saturated fat. This is a serious concern because trans fat is far more dangerous than saturated fat, not less dangerous. The FDA proposal would convey to people the opposite of the truth.

In addition to the false and misleading packaging which the FDA condones under its regulatory regime, there is an abundance of anecdotal evidence that food manufacturers are refusing to provide consumers with information about the trans fat in their products. There is even a report that Kraft has refused to disclose the amount of trans fat in its Oreo cookies on the ground that such information is "classified."
(<http://fitamerica.com/famd/opages/10topfoods.asp>)

Customers need readily accessible information about trans fat in the products that they are buying without any further undue delay. Lives are at stake. Newly printed labels will take time to reach store shelves while old stock is sold. Therefore, to avoid any unnecessary further deception of consumers, Petitioner requests that the FDA require that all food manufacturers disclose on the Internet and via a toll free telephone number the trans fat contents of each of their products, accompanied by a statement that "intake of trans fat should be as low as possible." Food manufacturers would be required to implement this requirement as soon as possible, and no later than July 1, 2003.

People are surprised and shocked when they learn about the existence and hazard of trans fat in the food that they have been consuming. For example, one person sent the following e-mail to Petitioner:

"I was unaware of trans fats myself. I have always been a label reader but never knew to look for hydro oils as a substance to avoid. It is scary to think how long I have been consuming trans fat against my will. I hope that the FDA's new labeling gets the support it needs to become a law."

Here is an e-mail from a man who found out that a product that he was eating regularly contained unlabeled trans fat:

to whom it may concern

i tell you, i'm shaking right now!!!!!!

i suffered my first heart attack at age 30, a coronary bypass surgery as well in 1985. since.....i have been eating triscuits by the box full along with wheat thins, in the sincerest belief that i was doing myself good.

until this minute, i continued with that belief.

in january, i had my second bypass.

god i just can't believe it.

i really want to cry.

The box of Triscuit Thin Crisps, states as follows underneath a graphic of the USDA Food Guide Pyramid:

“Triscuit Thin Crisps are part of the “Bread, Cereal, Rice and Pasta Group.” Nutrition experts recommend eating the most from this important group: 6-11 servings daily.”

The box also states "No Cholesterol," "Low Saturated Fat." The Nutrition Facts panel shows that there is 1g of saturated fat per serving. There is no mention on the box that the product contains up to 2.5g of trans fat.

The packaging and labeling of Triscuits is a deception that Kraft/Nabisco presumably believes is permitted under current FDA regulations. There can be no justification for the FDA's proposal to allow this kind of deception by Kraft and other food manufacturers to continue until 2006 purportedly for the sake of protecting small businesses or for any other reason. The man who sent the e-mail regarding the Triscuits has the right to know what he is eating. The FDA should protect him. That is why the Nutrition Labeling and Education Act of 1990 was enacted.

Let us look at another product - Esteem Sugar Free Creme Wafers (chocolate). This is obviously a product that diabetics will consume believing that it is safe for them because it is sugar free. The Nutrition Facts panel on the product indicates that it contains 1.5g of saturated fat per serving. There is no mention of the fact that the product may contain as much as 4g of trans fat per serving. This deception is of great concern because of the link between trans fats and diabetes. It is difficult to understand how the FDA can defend this kind of dangerous practice.

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There is a public perception, which is evident in many of the e-mails that Petitioner has received, that the FDA is insensitive to the human impact of the trans fats issue and is not representing the interests of the consumer. The perception is correct.

The FDA is not discharging its statutory responsibility under Section 2(b) of the Nutrition Labeling and Education Act of 1990 to require proper labeling. Petitioner requests that the FDA review its thinking and policy on this issue and act in the interests of the American people, decisively and quickly.

ENVIRONMENTAL IMPACT STATEMENT

No environmental impact analysis is required in support of this Petition, and the granting of this Petition would not have any environmental impact.

CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this Petition includes all information and views on which the Petition relies, and it includes representative data and information known to Petitioner which are unfavorable to the Petition.

PETITIONER



Dated: May 22, 2003

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