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**TO THE U.S. FOOD AND DRUG ADMINISTRATION**

**DOCKET NO. 03N-0076; RIN 0910-AC50**

**COMMENTS ON  
ADVANCED NOTICE OF PROPOSED RULEMAKING  
REGARDING TRANS FAT LABELING**

## **INTRODUCTION**

These comments are made in response to the Advance Notice of Proposed Rulemaking (“ANPR”) published in the Federal Register on July 11, 2003. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at page 41507.]

## **ABOUT OUR ORGANIZATION**

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

On May 1, 2003, we filed a lawsuit against Kraft Foods North America, Inc. seeking an injunction against the sale and marketing of Oreo cookies containing trans fat to children in California. As a result of the lawsuit, Kraft announced that almost across the board, it would eliminate trans fat, or cut it to about half a gram per serving in cookies and crackers. As we were successful in achieving our goal, we voluntarily dismissed the lawsuit.

There was enormous national publicity during the week of May 12, 2003 regarding the lawsuit. Tens of millions of people who were previously unaware of the presence and danger of trans fats in their food products suddenly became aware, and word is continuing to spread.

On May 14, 2003, a poll was conducted by America Online regarding the lawsuit. 655,296 people voted. 26% responded that “something needs to be done” about the trans fat problem. This is a very substantial percentage – a quarter of the population. We believe that if a poll were taken of women only, the percentage would be much higher

judging by the e-mail that we have received. This is important, because women are more likely than men to be the food purchasers for families.

Our website has been visited more than 140,000 times since May 12, 2003. Approximately, 75,000 visits have occurred since we dismissed the lawsuit. Hundreds of people visit the website every day. In fact, it would be fair to say that it is now the leading trans fat website in the world. A Google or Yahoo search for “trans fat” or “trans fats” will bring up our website at the top of the list. This is important because it means that we are almost certainly receiving more e-mail from people interested in the trans fat issue than any other governmental or non-governmental organization. We are able to assess the views of consumers simply by reading the thousands of e-mails that they have sent to us.

The e-mails that we have received show that the American people are deeply concerned and very angry about the presence of trans fat in food and the lack of proper labeling. A selection of the e-mail is posted on our website, which we urge the FDA to review. It is a very valuable source of consumer research.

We have not posted on the website the hundreds of e-mails that we have received from people who are confused by lists of ingredients that indicate the presence of partially hydrogenated oil, but zero grams of trans fat. However, we will be happy to provide such e-mails available to the FDA upon request (with names removed).

**THE FDA’S MANDATE IS TO PROTECT  
THE PUBLIC, NOT THE FOOD INDUSTRY**

Under the Nutrition Labeling and Education Act of 1990, 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.”

There is a timing element implied in the statutory mandate. Unnecessarily deferring mandatory labeling until 2006 violates the mandate. Trans fat labeling was first proposed by the FDA as long ago as November 1999. The FDA has estimated that 2,100 to 5,600 lives each year are being lost as a result of the bureaucratic delay. [Fed. Reg., Vol. 64, No. 221, November 17, 1999 at page 62772.]

Walter Willett, M.D. of the Harvard Medical School, who is widely acknowledged as one of the world’s leading experts on nutrition, estimates that 30,000 or more cases of coronary heart disease are caused each year in this country by trans fats. [*Eat, Drink, and Be Healthy: The Harvard Medical School Guide To Healthy Eating* by Walter C. Willett, M.D, at p. 73.]

The FDA’s explanation is that the delay is necessary “to minimize the need for multiple labeling changes and to provide additional time for compliance by small

businesses to allow them to use current label inventories and phase in label changes.” [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41466.] We are completely unimpressed by this explanation, and so too are large numbers of our supporters who have made their views known to us by e-mail. We feel compelled to remind the FDA that the statute requires the FDA to protect “the public,” not the food industry. The FDA has elevated an extremely minor commercial issue - preprinted label inventories - above its statutory responsibility to save lives and prevent disease. The FDA’s state of mind concerns us and our supporters greatly. The FDA needs to work on rebuilding trust with consumers.

While the FDA’s decision on the timing issue is now behind us, the FDA in the ANPR is inviting comments about unresolved trans fat labeling issues. However, the initial signs in the ANPR are worrying. The six footnote options on which the FDA is seeking comments look like they were written by the food industry, or to appease the food industry.

The FDA should solidly resist food industry pressure to underinform or misinform consumers, in violation of the statute and the FDA’s moral responsibility.

### **SPECIFIC COMMENTS**

#### **1. THE FOOTNOTE ISSUE**

In 2002, the National Academy of Science’s Institute of Medicine issued a report entitled *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids* (hereinafter the “NAS Report”). The NAS Report’s conclusion was as follows:

“There is a positive linear trend between trans fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD, thus suggesting a Tolerable Upper Intake Level (UL) of zero. Because trans fatty acids are unavoidable in ordinary diets, achieving such a UL would require extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods, such as dairy products and meats, that contain *trans* fatty acids may result in inadequate intakes of protein and certain micronutrients) and unknown and unquantifiable health risks may be introduced by any extreme adjustments in dietary pattern. For these reasons, no UL is proposed. Nevertheless, it is recommended that trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.” (Emphasis added.)

Based on the NAS Report, the FDA proposed in November 2002 that instead of a Daily Value, an asterisk would be placed on the right-side of the trans fat line of the Nutrition Facts panel directing the consumer to the following footnote:

**INTAKE OF TRANS FAT SHOULD  
BE AS LOW AS POSSIBLE.**

In July 2003, the FDA abandoned its position saying that “the overwhelming majority of comments opposed the use of the footnote.” [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at page 41452.] It would appear that the FDA may have been swayed by the number of comments rather than the contents of those comments. The food industry is obviously far better prepared to flood the FDA with comments than the unorganized and uninformed public. The FDA should be concerned with what people say, not how many people say it.

The FDA, in its ANPR, has now invited public comments on six footnote options. We discuss each in turn.

**FDA FOOTNOTE OPTION ONE**

**INTAKE OF SATURATED FAT AND TRANS FAT  
SHOULD BE KEPT LOW WHILE MAINTAINING A  
NUTRITIONALLY ADEQUATE DIET.**

**COMMENTS**

A. We object to the omission of the words “as low as possible.” Those words were drawn directly from the NAS Report and are not in any way confusing. They are supported by the comprehensive and solid medical and statistical evidence cited in the NAS Report. The message is totally valid: try to avoid trans fat if you can.

The argument that the words “as low as possible” would result in consumers steering away from products containing naturally-occurring trans fatty acids is a red herring. The problem is not naturally-occurring trans fatty acids. The problem is partially hydrogenated oils. Adding the words “while maintaining a nutritionally adequate diet” would send an appropriate message to consumers that they should adopt a balanced diet and not take extreme actions which might compromise their health.

B. The word “low,” standing alone, is meaningless. It begs the question – how much is “low”? “Low” can only be understood in relation to quantifications of “low” and “high.” “Low” could be 2 grams, 10 grams, or 50 grams. Consumers will not find the word “low” helpful in any way. The statute requires the FDA to establish labeling which advises consumers of the “relative significance” of nutrient information “in the context of a total daily diet.” The word “low” standing alone does not convey “relative significance” at all.

C. The purpose of the footnote is to compensate for the fact that there would be no percentage Daily Value on the trans fat line. There is a percentage Daily Value for saturated fat and therefore no need for a footnote about saturated fat.

D. We are very concerned with, and would object to, identification of trans fat with saturated fat. We need only look to the FDA's own findings in support of the Final Rule on trans fat labeling in July 2003 for support:

The agency acknowledges that declaring the amount of saturated fat and trans fat together, even with the proposed footnote, could lead some consumers to believe that the two types of fatty acids are chemically and physiologically the same. Clearly, trans fats contain double bonds and thus, are chemically distinct from saturated fat. Likewise, although both saturated and trans fats do raise LDL-C levels, physiologic distinctions between the two types of fatty acids do exist as discussed previously in Comments 10 and 11. Clearly, trans fats contain double bonds and thus, are chemically distinct from saturated fat. Likewise, although both saturated and trans fats do raise LDL-C levels, physiologic distinctions between the two types of fatty acids do exist as discussed previously in Comments 10 and 11. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41453.]

Accordingly, the agency concludes that it is necessary to disassociate saturated and trans fats on the nutrition label so that consumers do not misinterpret the declaration of saturated fat by thinking that trans fats are included in that definition. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41453.]

The agency is persuaded by the large number of comments on this issue that the proposed action was, in fact, interpreted by many as incorrectly classifying the two different fatty acids as "saturated fat" and that it is necessary to disassociate trans fat from saturated fat to prevent misleading consumers in this way. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41456.]

The wording of Option One would equate trans fat and saturated fat in the minds of consumers, and would lead many consumers to believe that they are exactly the same. However, as the FDA acknowledged, trans fat is chemically distinct from saturated fat. The FDA found that the association of trans fat and saturated fat would mislead consumers. We agree.

**FDA FOOTNOTE OPTION TWO**

**INTAKE OF TRANS FAT SHOULD BE KEPT LOW WHILE MAINTAINING A NUTRITIONALLY ADEQUATE DIET.**

COMMENTS

See Comments A and B on Option One.

**FDA FOOTNOTE OPTION THREE**

**INTAKE OF SATURATED FAT, TRANS FAT AND CHOLESTEROL SHOULD BE KEPT LOW WHILE MAINTAINING A NUTRITIONALLY ADEQUATE DIET.**

COMMENTS

See Comments A, B, C and D on Option One.

A. We believe that addition of the word “cholesterol” adds even more confusion. As the FDA has pointed out, associating trans fat and saturated fat in the minds of consumers is misleading. Associating a third element, cholesterol, only compounds the problem.

**FDA FOOTNOTE OPTION FOUR**

**AS PART OF A NUTRITIONALLY BALANCED DIET, INTAKE OF SATURATED FAT, TRANS FAT, AND CHOLESTEROL SHOULD BE KEPT LOW.**

COMMENTS

See Comments A, B, C and D on Option One and Comment A on Option Three.

A. We object to Option Four because it makes it appear that trans fat is a beneficial and necessary part of a nutritionally balanced diet. The message is so perverse that consumers could be expected to increase trans fat input. Trans fat is not a necessary part of any diet. It has no known beneficial effects. The FDA found as follows:

FDA finds that the intervention and observational studies provided strong evidence of both a causal relationship between trans fat intake and risk of CHD and applicability

to the general U.S. population. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41446.]

**FDA FOOTNOTE OPTION FIVE**

**HEALTHY DIETS START WITH DIETS LOW IN SATURATED FAT, TRANS FAT, AND CHOLESTEROL.**

COMMENTS

See Comments A, B, C and D on Option One, Comment A on Option Three, and Comment A on Option Four.

A. We object to Option Five because it makes it appear that trans fat is “healthy” and a necessary part of a nutritionally balanced diet. It sounds like an advertisement for trans fat.

**FDA FOOTNOTE OPTION SIX**

**NUTRITIONALLY ADEQUATE DIETS INCLUDE DIETS LOW IN SATURATED FAT, TRANS FAT, AND CHOLESTEROL.**

COMMENTS

See Comments A, B, C and D on Option One, Comment A on Option Three, Comment A on Option Four, and Comment A on Option Five.

**OUR PROPOSED FOOTNOTE OPTIONS**

Our proposed footnote options, in order of preference, are as follows:

**OUR FOOTNOTE OPTION ONE**

**INTAKE OF TRANS FAT SHOULD BE AS LOW AS POSSIBLE.**

[The footnote could be omitted when there is no partially hydrogenated oil whatsoever in the product.]

## COMMENTS

This is the footnote that the FDA has apparently rejected. Nevertheless, it is clear, concise, and valid. It is based on the NAS Report. We strongly urge the FDA to reconsider its rejection of this wording. The words “as low as possible” are an essential part of any footnote. We believe that the words “as low as possible” are legally required in view of the FDA’s findings about the dangers of trans fat and the NAS Report.

The food industry is expressing “concern” that consumers will avoid meat and dairy products because they contain naturally-occurring trans fat. We believe that this “concern” is bogus. However, the FDA could allow the footnote to be omitted when there is no partially hydrogenated oil whatsoever in the product.

### **OUR FOOTNOTE OPTION TWO**

**THIS PRODUCT CONTAINS PARTIALLY  
HYDROGENATED OIL. INTAKE OF TRANS FAT  
FROM SUCH OILS SHOULD BE KEPT AS LOW AS  
POSSIBLE.**

**[The footnote could be omitted entirely when there is no partially hydrogenated oil whatsoever in the product.]**

## COMMENTS

This wording would address any concern about consumers avoiding meat and dairy products because they contain naturally-occurring trans fat. It would also inform consumers about the connection between partially hydrogenated oils and trans fat, which is a positive and important educational step.

### **OUR FOOTNOTE OPTION THREE**

**INTAKE OF TRANS FAT SHOULD BE KEPT AS  
LOW AS POSSIBLE WHILE MAINTAINING  
A NUTRITIONALLY ADEQUATE DIET.**

## COMMENTS

This option is far less preferable than our other two options. Our concern with this option is that it seriously dilutes, weakens and confuses the message about trans fats. However, if adding the words “while maintaining a nutritionally adequate diet” is the price that we have to pay to obtain acceptance of the words “as low as possible,” then as a matter of practical politics it may be a price worth paying.



## **2. TRANS FAT-FREE CLAIMS**

We have received more e-mail about products that list a partially hydrogenated oil in the ingredients, but show zero grams of trans fat or claim to be trans fat-free, than any other subject. We have now taken steps to make sure that visitors to our website clearly understand that the law provides that if a product contains less than 0.5 grams of trans fat, the content must be expressed as zero, except when the statement “Not a significant source of trans fat” is used.” It is unfortunate that they have to rely on our website to clear up their understandable confusion.

We are not concerned with fine and meaningless distinctions between stating that a product has zero grams of trans fat and claims that it is trans fat-free. As far as the consumer is concerned, they mean exactly the same thing – that the product contains no trans fat. We are not confident that the FDA appreciates this point.

We are surprised and puzzled at the FDA’s issuance of the rule requiring rounding down to zero, because it is totally inconsistent with the following findings made by the FDA as the basis for the Final Rule:

As the agency has explained earlier, consumers need information about trans fat on all foods, not just those that contain a certain threshold level of trans fat, to reduce overall intake of trans fat in the diet. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41439.]

Consumers need to know when a product contains less than 0.5 g trans fat just as much as they need to know when a product contains 1, 2, or more grams of trans fat in order to understand how each product impacts their overall dietary intake of trans fat. Such need is not based solely on the presence or absence of claims, levels of other fats, or declaration of other fats on the label. Consumers need to understand how each product contributes to their overall intake of trans fat in order to maintain healthy dietary practices which call for reducing trans fat intake as low as possible while consuming a nutritionally adequate diet. Consumption of several foods, each with 0.5 to 1 g trans fat per serving, over the course of a day may result in a significant overall trans fat intake for the day. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41451.]

It is the provision of trans fat information on foods consumed throughout the day that can assist consumers in maintaining healthy dietary practices, and the usefulness of this information is not limited to foods with certain

nutritional characteristics. In addition, the consumption of several foods with 0.5 or 1 g of trans fat per day that may provide a total of 8 g of trans fat to the diet would be expected to have the same effect on LDL-C levels as consumption of one food with 8 g trans fat. Requiring trans fat to be declared only when present at a specified level would be inconsistent with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of the amount. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41451.]

The agency believes that the absence of information of the amount of trans fat in a product, when labeling of trans fat as a mandatory nutrient is required, even where trans fat is present at less than 0.5 g, would be misleading. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41451.]

The FDA in its Final Rule is requiring that if the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. This makes no sense at all in view of the FDA's findings. It is misleading, arbitrary and capricious, and violative of the statute.

Here are some of the unsolicited e-mails that we have received from the public on this subject:

I saw a package of Doritos that has a statement on the front of the bag saying it contains zero grams of trans fats. Yet the ingredient list includes the words "partially hydrogenated." Can they do that? Is the amount so minimal it doesn't add up to a single gram and that's the logic behind the statement?

\* \* \*

I have written to the 'dietician' at Take Control (butter substitute/spread) with this question: The label says that there are no trans fatty acids. However, it also says that Take Control contains partially hydrogenated soybean oils. Wouldn't that process produce trans fats? I have not received an answer from them. Hope you can help. It has been such a struggle with high cholesterol, LDL, in spite of exercise, a basically vegetarian diet, etc.

\* \* \*

I recently found your website and was curious. You said that Frito Lay was getting rid of trans fat in their products. I just grabbed a Cheetos bag and while it says 0g Trans Fat, the ingredients include partially hydrogenated soybean oil. Can you clear this up for me?

\* \* \*

How is it that the nutritional facts statement says 0 grams of Trans Fats but the ingredients list partially hydrogenated soy oil? Doesn't partially hydrogenating oil create trans fats? Hope you can offer some insight.

\* \* \*

I noticed recently that some Frito Lays potato chips are showing trans fat contents and some have a "stamp" at the front of the package saying "... 0 g trans fat". When reading the ingredients, it was found that the BBQ flavored (code 0 28400 01473 1) has partially hydrogenated soybean oil listed in the ingredients, despite the flashy "stamp" at the front saying its free of trans fats. The regular flavor was OK, no trans-fats were listed in the ingredients (code 0 28400 01472 1). A small package bought at "Rolly Polly" in NE atlanta suburb had the same deceiving "stamp" and trans fat included in the ingredients. I tried to call Frito Lays and complain, but the line is always busy (800-352-4477). This cannot continue. Now it is "in your face" fraud.

\* \* \*

I just munched on some Frito Lay Doritos and in the Nutrition facts, it says no Trans Fats. Yet in the ingredients, it has partially hydrogenated soybean oil listed. Is that because the serving is so small that it's too minimal to list? I hope we are going to be able to trust the labels to tell the truth!

\* \* \*

I have a question about the labeling. I bought Jolly Time's Health Pop at Shop Rite last night. I bought it because it stated that it was Trans fat free, but then when I got home I read the ingredients and it says that it has partially

hydrogenated soybean oil. I am confused. Does it have Trans fat? It is okay if I do not get a response. I kind of know the answer. Companies should not be allowed to false advertise if this product is not Trans fat free.

\* \* \*

I just purchased "Jolly Time Healthy Pop Butter Flavored" microwave popcorn. I bought it, because right on the front cover, it says "Trans Fat Free". However, when I got home and looked at the ingredients, it clearly states, "Partially Hydrogenated Soybean Oil".

How can these companies sell their products on the bandwagon of Trans Fat Free when they aren't in fact trans fat free? Isn't this a case of false advertising? Is there anything that can be done about this? I wrote to the company, but I am sure they don't care what one customer thinks. I am taking the popcorn back to the store. Thanks for your time.

\* \* \*

Not sure if you guys already knew this, but Jolly Time is guilty of false advertising. I just bought a box of Jolly Time - Healthy Pop "TRANS FAT FREE" popcorn. Its there as plain as day on the label. However the second ingredient is, guess what? Partially Hydrogenated Soybean Oil. What could they possibly be thinking? I have made a complaint on their website and placed a Better Business Bureau complaint on American Pop Corn Company in Sioux City, IA, the makers of Jiffy Pop (says so on the box). What they are doing considered a misdemeanor. And, they can't claim that they don't know what a TF is.... I would like your help in nailing these guys. I'm so livid I could scream!

\* \* \*

PLEASE do not allow items labeled 'trans fat free' if there is ANY in there at all! I have to seriously watch my intake and it would very confusing to me if I saw 'trans fat free' and it still had .45 grams in there!

The public needs to have this issue clarified, on the label. Therefore, we propose that the following statement be added at the beginning of the footnote whenever partially hydrogenated oils are listed in the ingredients, but the trans fat content is shown as zero grams:

**THIS PRODUCT CONTAINS TRANS FAT  
IN AN AMOUNT LESS THAN 0.5 G PER SERVING.  
CONSUMPTION OF SEVERAL SERVINGS MAY  
RESULT IN A SIGNIFICANT OVERALL TRANS  
FAT INTAKE.**

This proposed wording will clearly inform the public and should prevent them from being misled. It is a necessary corrective measure. It is based on the FDA's own finding that "consumption of several foods, each with 0.5 to 1 g trans fat per serving, over the course of a day may result in a significant overall trans fat intake for the day." [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41451 (emphasis added).]

"Trans fat-free," "zero grams of trans fat," or substantially similar claims, claims should be prohibited whenever any trans fat is present.

### **3. THE TIMING ISSUE**

The current state of affairs is that food manufacturers are permitted to state the trans fat content of their products on the Nutrition Facts panel, with a blank space instead of a Daily Value. This is a dangerous situation, because consumers are very likely to interpret this as meaning that they can consume unlimited amounts of trans fat without any adverse consequences. It is also, unquestionably, a violation of the statutory requirement that the "relative significance" of the trans fat content be stated. Therefore, we request that the FDA move forward with a Proposed Rule and the Final Rule as soon as possible. Delay is costing lives.

### **CONCLUSION**

Finally, we quote the FDA once again:

These survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of trans fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect and want to find this information. If they cannot find information on trans fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely

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to be misled about a food's basic characteristics. [Fed. Reg., Vol. 68, No. 133, July 11, 2003 at 41450.]

The FDA's decisions on trans fat labeling will affect consumers for many years to come, probably decades. Millions of lives will be affected by the FDA's decisions on what goes on the label. People will suffer heart attacks and die unnecessarily if the FDA breaches the public trust and makes the wrong decisions.

We strongly urge the FDA to act only in the best interests of the consumer and not allowed itself to be swayed by bogus concerns expressed by the food industry that are designed to prevent consumers from receiving the information that they need.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen L. Joseph". The signature is stylized with overlapping loops and a prominent horizontal stroke at the top.

Stephen L. Joseph  
Chief Executive Officer

SLJ/sel