

BANTRANSFATS.COM

**3701 SACRAMENTO STREET #500
SAN FRANCISCO
CALIFORNIA 94118**

Phone: 415-577-6660

Fax: 415-869-5380

E-mail: bantf@earthlink.net

Website: www.bantransfats.com

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TO THE U.S. FOOD AND DRUG ADMINISTRATION

DOCKET NO. 2003N-0076

**SUPPLEMENTAL 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 March 1, 2004. [Fed. Reg., Vol. 69, No. 40, pages 9559-60.]

These comments supplement the comments that BanTransFats.com, Inc. submitted on October 9, 2003 as part of Docket # 03N-0076.

THE FDA NEEDS MUST ADDRESS THE DIFFERENCE BETWEEN TRANS FATS IN ANIMAL PRODUCTS AND TRANS FAT IN PARTIALLY HYDROGENATED VEGETABLE OILS

The NAS/IOM and the FDA constantly fail to take into account the known differences between trans fats in animal products and trans fats in partially hydrogenated vegetable oils. Animal sources of trans fat are chemically different and have different physiological effects than the trans fat produced by the partial hydrogenation of vegetable oils. It is this organization’s position that partially hydrogenated vegetable oils should be banned.

By effectively and mistakenly merging the two types of trans fat, the FDA finds itself effectively promoting and approving partially hydrogenated oils, because it does not want to disapprove animal products. Until the FDA draws a distinction between the two types of trans fat, it will be unable to escape this trap.

The FDA should meet this issue head-on. A statement on the label such as the following would be helpful in sending the right message: “This product contains partially

hydrogenated oil which is a source of trans fat. Intake of such oil should be as low as possible.”

**A JOINT DV FOR SATURATED FAT AND
TRANS FAT WOULD VIOLATE THE NLEA**

We read with alarm that the FDA is considering a joint DV for saturated fat and trans fat.

Under the Nutrition Labeling and Education Act of 1990 (“NLEA”), 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.” While we recognize that the FDA’s rulemaking is entitled to a certain degree of deference, a joint DV would clearly violate the NLEA, because as the FDA has admitted, “trans fat and saturated fat are chemically distinct” and the FDA “acknowledges that research demonstrates different physiological effects among the fatty acids.”

A joint DV would indisputably send the following incorrect information to consumers:

- Trans fat and saturated fat are chemically exactly the same.
- Trans fat and saturated fat have exactly the same physiological effects.
- Consuming x grams of trans fat has exactly the same effect as consuming x grams of saturated fat.

It is virtually universally accepted that trans fat has additional and worse physiological effects than saturated fat. The effects of trans fat include the following:

- Lowers HDL cholesterol in a dose response manner (the higher the trans fat level in the diet, the lower the HDL cholesterol in the serum);
- Raises LDL cholesterol in a dose response manner.
- Raises the atherogenic lipoprotein (a) (Lp(a)) (whereas saturated fatty acids lower Lp(a)).
- Lowers the amount of cream (volume) in milk from lactating females, thus lowering the overall quality available to the infant.
- Causes a dose response decrease in visual acuity in infants who are fed human milk with increasing levels of trans fats.

- Correlates to low birth weight.
- Increases blood insulin levels in response to glucose load, increasing risk for diabetes.
- Affect immune response by lowering efficiency of B cell response and increasing proliferation of T cells.
- Decreases the response of red blood cells to insulin, thus having a potentially undesirable effect in diabetics.
- Inhibits the function of membrane-related enzymes such as the delta-6 desaturase, resulting in increased conversion of e.g., linoleic acid to arachidonic acid.
- Causes adverse activities in the activities of the important enzyme system that metabolizes chemical carcinogens and medications, i.e., the mixed function oxidase cytochromes P-448/450.
- Causes alterations in physiological properties of biological membranes including measurements of membrane transport and membrane fluidity.
- Causes alterations in adipose cell size, cell number, lipid class, and fatty acid composition.
- Adversely interacts with conversion of plant omega-3 fatty acids to elongated omega-3 tissue fatty acids.
- Escalates adverse effects of essential fatty acid deficiency.
- Increases peroxisomal activity (potentiates free-radical formation).
- Precipitates childhood asthma.

In the event that the DV rules in favor of a joint DV, we would challenge the ruling in court. We hereby formally object to a joint DV.

**MENU MODELING CANNOT ASSUME THAT INTAKE
OF PARTIALLY HYDROGENATED OILS IS ACCEPTABLE**

Any menu modeling used to develop a DV for trans fats should be based on a zero intake of partially hydrogenated oils. Such oils have no place in a nutritionally adequate diet.

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**OUR CONCERN ABOUT FOOD INDUSTRY
INFLUENCE AND THE MERGING OF DISSIMILAR FATS**

As stated above, the latest ANPR avoid two crucial distinctions: (i) the distinction between trans fat from animal products and trans fat from partially hydrogenated oils; and (ii) the distinction between trans fat and saturated fat. This “merging” of dissimilar fats plays right into the hands of those who would seek to keep partially hydrogenated oils in our food supply.

The FDA is urged to resist industry pressure. Under the NLEA, “the public” comes first.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen L. Joseph". The signature is somewhat stylized and scribbled.

Stephen L. Joseph
Chief Executive Officer

SLJ/sel