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**DATE OF CORRESPONDENCE:** 08/07/02

**DATE INTO FDA:** 08/13/02

**TO:** LESTER M CRAWFORD HF-I

**FROM:** MARGO G WOOTAN, D.SC. ET AL, CSPI, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

**SYNOPSIS:** URGES FDA TO CLUSTER TRANS FAT WITH SATURATED FAT ON NUTRITION FACTS LABELS AND USE A COMBINED DAILY VALUE, SIMILAR TO THE PROPOSED CANADIAN FORMAT (REF: DOCKET NO. 94P-0036/98N-0044).

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**COORDINATION:**

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**REFERRALS FROM HF-40**

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**Date:** 8/7/02

**Please deliver the following pages to:** Lester Crawford

**Name:** Dr. Lester Crawford, Deputy Commissioner

**Company:** Food and Drug Administration

**Fax number:** 301-443-3100

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**Sender:** Margo Wootan, Center for Science in the Public Interest  
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**Subject:** Docket No. 94P0036

**Comments:**

August 7, 2002

Dr. Lester Crawford  
Deputy Commissioner  
Food and Drug Administration  
5600 Fishers Lane, Room 1471  
Rockville, MD 20857

Re: Docket No. 94P0036

Dear Dr. Crawford:

Now that the Institute of Medicine's (IOM) *Report on the Dietary Reference Intakes for Trans Fatty Acids* is completed, we urge the Food and Drug Administration (FDA) to promptly finalize a trans fat labeling regulation and label trans fat together with saturated fat using the current Daily Value (DV) for saturated fat, similar to the format proposed by Canada (see attached).

As you know, the IOM report found that there is no known requirement for trans fat for specific physiologic functions. The report provides yet another confirmation that trans fat increases LDL cholesterol levels and the risk of coronary heart disease. Further, it found that the effect of trans fat on the LDL:HDL ratio is greater than for saturated fat.

The IOM concluded that the data suggest that the Upper Limit for trans fat should be zero. However, because eliminating all trans fat from the diet would be difficult and could have unintended, negative effects on diet quality, no Upper Limit was set. The IOM instead recommended that trans fat intake be as low as possible.

Given the IOM's report and recommendation, we urge the FDA to require a trans fat labeling format similar to that proposed by Canada (with the grams of saturated and trans fat labeled on separate lines but clustered together without an intervening rule and with a combined percent-Daily Value). That is similar to formats proposed by the FDA. The proposed regulation for trans fat labeling discussed several different labeling formats, including listing "Saturated + Trans Fat" on Nutrition Facts labels and using a combined percent-Daily Value for both fats (64 Fed. Reg. at 62755-62757 [November 17, 1999]). Thus, the FDA has authority to finalize such a regulation.

The Canadian format has the advantage of providing information about the gram amounts of each fat clearly and separately for those who want it. It also avoids any potential concerns raised about labeling trans fat as saturated. That format just clusters two, related categories of fats together.

The key advantage of the Canadian format is that it provides consumers with some context about how the combined amount of saturated and trans fat fit into a day's diet. Saturated and trans fat should be considered – and lowered – together to reduce the risk of heart disease. It would be counterproductive if the labeling format led consumers to increase their saturated fat intake while they reduced their consumption of trans fat, especially given that Americans consume

approximately five times more saturated than trans fat. Combined labeling also should provide a greater incentive for food manufacturers to reduce the total amount of saturated plus trans fat if they reformulate products. Finally, the Canadian format would make it easier to compare products. A consumer would not have to add up two separate lines (saturated and trans fat) on several different products to compare the amounts of fats that promote heart disease.

The FDA should use the current DV for saturated fat as the combined DV for saturated and trans fat. While the FDA laid out a strong rationale for such an approach in the proposed rule for trans fat labeling, that approach is bolstered by the IOM report. Since the IOM concluded that the Upper Limit for trans fat *should be zero*, the combined total of zero grams of trans fat plus 20 grams of saturated fat adds up to 20 grams of saturated and trans fat combined.

Labeling trans fat on a separate line without a Daily Value would not be consistent with either the letter or the spirit of the 1990 Nutrition Labeling and Education Act requirement that labeling help consumers understand the nutrition information of individual foods in relation to dietary recommendations (House Report 101-538, 100th Congress, 2<sup>nd</sup> Session, 1990, p. 18). Without putting the number into context, the gram listing of trans fat would be confusing and misleading. Numbers that consumers perceive to be low could represent meaningful amounts of heart-unhealthy fat. For example, a consumer might think that five grams of trans fat in a doughnut is not significant. However, that amount represents a quarter of the DV for heart-unhealthy fat (i.e.; of the current DV for saturated fat).

According to the FDA's own cost-benefit analysis, trans fat labeling has considerable potential to help Americans reduce their risk of heart disease. The FDA should require a labeling format that has the least chance of misleading consumers and the best chance of helping them to make heart-healthy choices. We strongly urge the Food and Drug Administration to cluster trans fat with saturated fat on Nutrition Facts labels and use a combined Daily Value, similar to the proposed Canadian format.

Respectfully,

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# Nutrition Facts

Serving Size 1 cup (200g)

## Amount Per Serving

Calories 280

**% Daily Value**

**Fat 13g** 20%

Saturated Fat 3g 25%  
+ Trans Fat 2g

Cholesterol 30mg 10%

Sodium 660 mg 28%

Carbohydrate 31g 10%

Fiber 0g 0%

Sugars 5g

Protein 5g

Vitamin A 4% Vitamin C 2%