

**ROUTING SLIP**  
**GENERATED BY: HF-40**  
**DATE: AUG 21, 2002**

**FDA CONTROL NUMBER** 02 4270

**TRACER #:**      **OS #:**

**DATE OF CORRESPONDENCE:** 08/15/02

**DATE INTO FDA:** 08/21/02

**TO:** LESTER M CRAWFORD HF-1

**FROM:** MEIR J STAMPFER, HARVARD SCHOOL OF PUBLIC HEALTH  
FRANK SACKS, MD, HARVARD SCHOOL OF PUBLIC HEALTH  
WALTER C WILLETT, HARVARD SCHOOL OF PUBLIC HEALTH

**SYNOPSIS:** COMMENTS ON TRANS FAT DOCKET # 98N-0044 - FDA'S PROPOSAL "TO AMEND ITS REGULATIONS ON NUTRITION LABELING TO REQUIRE THAT THE AMOUNT OF TRANS FAT PRESENT IN A FOOD BE INCLUDED IN THE AMOUNT AND PERCENT DAILY VALUE (%DV) FOR SATURATED FAT."

**LEAD OFFICE:** HFA-305

**HOME OFFICE:** HF-40

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**COPIES:** GENERAL DISTRIBUTION  
HF-1 LESTER M CRAWFORD  
HF-2 MURRAY M LUMPKIN  
HF-40 LAJUANA D CALDWELL  
HF-40 ANNE B CRAWFORD  
HFS-1 JOSEPH A LEVITT

**COORDINATION**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

<b>ASSIGNED TO</b>	<b>ACTION</b>	<b>DUE DATE</b>
----- HFA-305      BUTLERJ	----- NECESSARY ACTION	-----



# HARVARD SCHOOL OF PUBLIC HEALTH

Department of Epidemiology

15 August 2002

Dr Lester Crawford, Deputy Commissioner  
Food and Drug Administration  
5600 Fisher's Lane, Room 1471  
Rockville, Maryland 20857

Dear Dr Crawford,

We were delighted to learn that the FDA is moving forward with the rules for labeling foods for content of *trans* fat. If done properly, this would have a major impact on health with minimal effort on the part of individuals, and little disruption of food processing practices.

One proposal has been to combine the recommended range of intake of *trans* together with saturated fat. We agree with the intent behind the suggestion, and believe that it represents a good solution. However, it is not optimal. By lumping saturated and *trans* fats together, it sounds as though it is fine to eat up to the limit for those two combined, regardless of whether this constitutes *trans* or saturated fat. This obscures the difference in the adverse effect. If one examines just lipids alone, one finds that *trans* fat is about twice as bad, gram for gram, in having an adverse effect on the total-to-HDL ratio, because saturated fat, while raising LDL, also raises HDL. In contrast, *trans* fat raises LDL but lowers HDL. Moreover, from epidemiologic studies, the apparent adverse effect of *trans* is far greater than what one might predict based on the effects on lipids alone, probably due to perturbation in the metabolism of essential fatty acids. Combining *trans* and saturated fat could well lead producers to abandon the attempt to rid their products of *trans*, opting instead to treat it as the same as saturated fat. Saturated fat is a normal component of the diet, so we can never reduce this to zero, nor would it be desirable to do so. In contrast, *trans* fat from hydrogenated vegetable oils is not a natural component of the diet, and there is no reason we cannot eliminate it from the diet. This would probably be the simplest and easiest fix to improve cardiovascular health for our country. The Canadian model represents a compromise for this solution.

Based on the recent IOM report that summarized a large body of data, the optimal label for *trans* would include the *trans* content, separated from saturated fat, with the notation that the recommendation is to eat as little as possible. The label should not simply be left blank, leaving the consumer to wonder that there is no upper or lower bound. Consumers should be informed that the consensus of the scientific community, based on a wide range of data, including randomized trials in humans for metabolic endpoints, concludes that we should eat as little *trans* as possible, and attempt to eliminate it completely from the diet. Thus the recommended range of intake for *trans* would be zero. If one follows the alternative line of reasoning, for example, a bottle of olive oil would have a larger saturated-plus-*trans* content (though it has no *trans*) than some baked goods whose fat is mostly hydrogenated vegetable oil. This makes no sense from a health or physiological perspective.

Yours sincerely,

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Professor of Cardiovascular Disease Prevention  
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