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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MA 20852

Docket No. 94P-0036

To whom it may concern:

This letter is written in response to the proposed rule "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims".

I would like to express overall support for the proposed rule. Given the weight of the accumulated data with respect to *trans* fatty acids and plasma cholesterol levels I think the time has come to include this class of fatty acids as part of the information provided in the Nutrition Facts panel of foods.

More specifically, I would like to express support for the proposal to list both types of cholesterol-raising fatty acids, saturated and *trans*, together as one number referred to as saturated fat, along with an asterisk and footnote to indicate the actual amount of *trans* fatty acids. The reasons for supporting this proposal are that the emphasis will remain on saturated fat, the component of the diet which contributes the majority of the dietary fatty acids that raise blood cholesterol levels, and the message will be simple and consistent with that of a number of health organizations, thereby reinforcing rather than complicating the current recommendations.

With regard to some of the specific queries within the proposed ruling, I don't think the approach described would detract from current health programs, such as that of NCEP. In fact, by combining saturated and *trans* fatty acids into one number labeled saturated fat, I think the ruling would support current health programs by not necessitating changes in terminology. Additionally, I do not think including *trans* with saturated fatty acids requires a change in the guidelines to consume a diet with  $\leq 30\%$  fat and  $< 10\%$  saturated fat.

For those that are interested or in the event that further research suggests separate guidance is necessary for saturated and *trans* fatty acids I think requiring the footnote "Includes \_\_\_ g *trans* fat" is advisable. This provides all the information without requiring the consumer to make food purchasing decisions on the basis of additional numbers or necessitating health programs to develop a new guideline for *trans* fatty acids. Along this same line, on the basis of current information, I do not feel there is sufficient data with which to develop a D.V. for *trans* fatty acids. Therefore, it is

unclear what guidance the consumer could be given with regard purchasing choices beyond focusing on the saturated fat number.

The proposed definition, "unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration" adequately identifies the fatty acids intended to be covered by the rule.

I do not think the FDA should allow the claim "*trans*-free" because it would create a disconnect between the labeling system (saturated fat + *trans* denoted as saturated fat) and the health claim, hence create unnecessary confusion.

It would appear that the other aspects of the proposed ruling, regarding issues like minimum levels of *trans* fatty acids for reporting and the tying of *trans* fatty acid levels to cholesterol free and low saturated fat claims is appropriate.

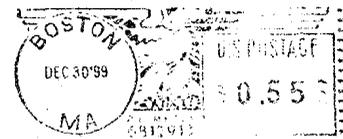
Since, if enacted, this ruling will result in a change in the type and amount of information presented to consumers, and because the implication of the change will not necessarily be intuitively clear to the consumer, I strongly suggest that the Food and Drug Administration facilitate in any manner possible a consumer education program regarding the change in the food labeling regulations and how to use the revised information.

Sincerely,



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