FOOD MARKETING INSTITUTE

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December 29, 2005

Robert Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration, HFS-1
5100 Paint Branch Parkway
College Park, MD 20740

Re: Trans Fat Labeling Implementation

Dear Dr. Brackett:

I am writing to urge that FDA undertake a reasoned and risk-based approach to enforcing the new trans fat labeling requirement which takes effect on January 1, 2006 for food products shipped in interstate commerce. The Food Marketing Institute (FMI) represents the nation's leading retail food establishments. Our members provide the full spectrum of packaged food products to millions of American consumers every day. We share your interest in providing consumers with accurate information so they can make informed purchasing decisions.

As you know, changing the labels of the many thousands of existing packaged food products is an enormous undertaking. While everyone in the food industry of whom we are aware is making a diligent effort to do so, we also hear a growing level of concern that every company may not be able to meet the January 1st deadline for every product. We know the agency has recognized this also, and we applaud your Center for issuing the recent guidance document on submitting requests for extensions, on a case-by-case basis, for products with 0.5 grams or less of trans fat per serving.

Nevertheless, we understand there is a sizeable backlog of those requests, and that companies who have submitted them and are awaiting a response are left in an uncertain state. We are also aware of a number of other requests that your agency has received for more broad-based extensions. As the trade association whose members have direct contact with the nation's consumers at the point-of-purchase, we suggest the following simple steps for you to consider:

1. Announce that FDA will be enforcing the trans fat labeling in a risk-based manner under a priority system based on the following type of schematic:

    a. Highest priority – Food products with over 2.0 gram of trans fat per serving.

b. Middle priority – Food products with over 0.5 grams of trans fat per serving, up to and including 2.0 gram of trans fat per serving.

c. Lowest priority – Food products with 0.5 grams or less of trans fat per serving.

2. Announce two useful clarifications to the recent guidance on seeking case-by-case extensions:

a. State that no enforcement action will be taken for products with 0.5 grams or less of trans fat for which an extension request is pending with the agency; and

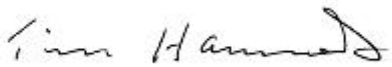
b. State that if a request for extension is denied, then the agency would provide a reasonable period of time (e.g., 3 months) for the company to come into compliance.

Taken together, we believe these steps would send several important messages. First, that the agency is going to give the greatest attention to the products containing the highest levels of trans fat. These are the products on which consumers are most in need of accurate information about trans fat content in order for those consumers to make sound, informed purchasing decisions. Second, that companies who have submitted extension requests in good faith can rest assured that they are not in jeopardy of an enforcement action while the request is pending or, if denied, for a reasonable time thereafter. This is a question of fundamental fairness. Finally, implementing these recommendations would continue to position your agency as being transparent in your approach and practical in ordering your own priorities.

The transition to comprehensive coverage of trans fat labeling on all food products will reasonably take time. Even if every company were in compliance with the January 1st effective date, that effective date is tied to initial introduction into interstate commerce, so that many products meeting that deadline will still not reach store shelves for several months, or more. The steps recommended above would fit comfortably within what is already designed to be a phased-in approach well into 2006, but will assure consumers they will have the most important information earlier and provide companies with a transparent understanding of the government's enforcement posture during the transition period.

We thank you very much for your prompt attention to these recommendations. We would be pleased to discuss this with you at the upcoming January 26 meeting of Center and FMI staff (or sooner) if that would be useful to the agency.

Sincerely yours,



Tim Hammonds
President and CEO

Cc: Dr. Andrew von Eschenbach
Acting Commissioner, FDA