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APR 14 2004 5:11:04 PM

VIA MESSENGER

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advanced Notice of Proposed Rulemaking – Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements, Reopening of Comment Period; Docket No. 2003N-0076

Dear Sir or Madam:

Enclosed you will find an original and two copies of a comment being submitted on behalf of the American Palm Oil Council regarding the above-referenced docket. Please date stamp one of the copies and return to our office with the messenger.

If you have any questions, please feel free to contact me at (202) 955-6658. We thank you in advance for the opportunity to address the FDA regarding this important issue.

Sincerely,



Doreen L. Manchester

DLM/lcj
Enclosure

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Dear Sir or Madam:

On behalf of the American Palm Oil Council (“APOC”), we thank the Food and Drug Administration (“FDA”) for this opportunity to respond to FDA’s advanced notice of proposed rulemaking and reopening of the comment period “Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,” 69 Fed. Reg. 9559 et seq. (March 1, 2004) (“ANPRM”).

In response to scientific evidence concerning health risks posed by *trans* fats, FDA and other public health organizations recently have taken steps to begin to reduce *trans* fat consumption by the American public. In July 2003, FDA issued final rules requiring food labels to disclose separately saturated and *trans* fat content.¹ This action improved the food labeling regulations, which previously failed to require disclosure of *trans* fat content.

We are responding specifically to FDA’s request for comments regarding its decision against publication of a % DV for *trans* fat or a combined % DV for saturated and *trans* fat, in light of a recent report by the Institute of Medicine of the National Academy of Science (IOM/NAS) (the “2003 IOM/NAS report”). FDA made the right decision, and should not change course. Additionally, FDA should require on labels of foods which contain *trans* fats a footnote advising consumers to keep intake of *trans* fats low while maintaining a nutritionally adequate diet.

¹ Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,433 (July 11, 2003) (*Trans* Fatty Acids in Nutrition Labeling).

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A. FDA Should Adhere To Its Decision Against A % DV For *Trans* Fat

In its July 2003 final rule, FDA, after careful consideration, decided against establishing a % DV for *trans* fat. FDA should not change course and adopt the contrary proposal in the 2003 IOM/NAS report. As noted in the ANPRM, the presence of *trans* fat “in the diet meets no known nutritional need.” The approach proposed in the 2003 IOM/NAS report – *i.e.*, to base an estimated % DV for *trans* fat on actual dietary intake data and menu modeling – is fatally flawed.

First, it is highly doubtful whether *trans* fat intake can be measured accurately enough to provide a meaningful % DV. There is a wide range of estimates of daily intake of *trans* fats, and only rough estimates of the breakdown between naturally-occurring and man-made sources.

Second, the IOM/NAS’s proffered rationale for a % DV is to provide a perspective about the presence of *trans* fats in foods so that consumers can compare products and make healthier food choices. There is a great danger, however, that consumers will misinterpret a % DV for *trans* as an acceptable, or even a minimum recommended, level of intake. Furthermore, as a practical matter, it will be difficult for consumers to apply sensibly a single daily reference amount, because *trans* fats commonly are consumed in slight amounts as minor components in prepared foods. It is hard to imagine consumers keeping a running daily “tally” of small amounts of *trans* fat consumed in numerous foods throughout the day. This problem is exacerbated by the fact that the July 2003 FDA rules appear to exempt from the *trans* fat disclosure requirement foods which contain 0.5 grams per serving or less of *trans* fats. Thus, even if consumers were able to keep track of *trans* fat consumption, they would not be aware of the full amount of intake due to underreporting on labels.

Third, adding a % DV for *trans* fat to food labels would overcomplicate and confuse what should be a clear, simple message – “reduce *trans* fat consumption.” The public health campaign to reduce *trans* fat consumption is still in its infancy. Just five years ago, FDA expressed concern that consumers did not know what *trans* fats were or know about their impact on health.² FDA and other public health organizations have just begun efforts to educate consumers and achieve a reduction in *trans* fat intake. It is too soon to begin trying to “fine tune” this message, especially given the doubtful utility of a % DV for *trans* fat.

² *Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 68 Fed Reg. 62746, 62,755 (Nov. 17, 1999).

B. FDA Should Adhere To Its Decision Against A Combined % DV For Saturated And *Trans* Fat

In promulgating the July 2003 final rule, FDA carefully considered whether to adopt a combined % DV for saturated and *trans* fat. FDA rejected this course of action, because it would be inconsistent with scientific evidence that saturated and *trans* fats have different chemical and physiological properties, and because it would be confusing to consumers.

The 2003 IOM/NAS report fails to provide any persuasive reason for FDA to change its considered decision. First, IOM/NAS points to consumer research showing that % DV's generally are helpful. This research, however, does not address the specific, and unique, issue of a combined % DV for saturated and *trans* fats. There are no other instances of combined % DV's. IOM/NAS fails to explain why FDA was wrong to conclude that the combined % DV will be confusing to consumers.

Second, IOM/NAS points to Canadian regulations. As FDA concluded in the July 2003 final rule, however, the Canadian regulatory regime is significantly different than FDA's, and IOM/NAS does not explain why FDA was wrong in the first instance.

Third, IOM/NAS asserts that a combined % DV would serve the "purpose" of not promoting one fat over another. This misses the point. The weight of scientific evidence is that *trans* fats are distinctly different than saturates, have at least as undesirable an impact on serum lipid profiles, and may well have even worse health impacts. Lumping *trans* fats together with saturates will be misleading to consumers. Even if *trans* fats were comparable to saturates in terms of health risks, special attention to *trans* still would be warranted. Public health efforts to reduce saturated fat intake have been underway for well over a decade, but the campaign to reduce *trans* fat consumption is in its infancy, as noted above.

Fourth, IOM/NAS argues that a combined % DV would be beneficial because it would give food manufacturers more flexibility. This proposition is dubious. If anything, food manufacturers are likely to bias formulations in favor of increased *trans* fat content, to take advantage of the apparent exemption in the July 2003 final rule from declaring any *trans* fat content below 0.5 grams per serving. Furthermore, any increased flexibility on the part of manufacturers would be outweighed by increased confusion on the part of consumers.

C. FDA Should Require A Footnote Regarding *Trans* Fat Consumption

In order to reinforce the relatively new message to reduce *trans* fat intake, FDA should require foods which contain *trans* fat to include a footnote on the Nutrition

April 14, 2004

Page 4

Facts label advising consumers that intake of *trans* fat should be kept low while maintaining a nutritionally adequate diet. Such a footnote will help establish in the minds of consumers the need to be attentive to foods which contain *trans* fats.

The footnote also will help remedy confusion caused by the loophole in FDA regulations (remedied by the July 2003 final rule) which allowed food manufacturers not to disclose *trans* fat. Suppose, for example, that a food product contains 1 gram/serving of *trans* fat, and 2 grams per serving of saturated fat. Under current FDA regulations, the label discloses the 3 grams/serving of total fat and 2 grams/serving of saturated fat, but not the *trans* fat content. The implication has been that, because it was not disclosed, the *trans* fat content was not a source of concern. The new regulations require disclosure of the 1 gram/serving of *trans* fat, and consumers will have to decipher this new information. The footnote will assist consumers in understanding that the (now disclosed) *trans* fat content is a matter of concern. The footnote also will assist consumers in choosing between products which contain *trans* fats, and those which do not.

* * *

American consumers are just learning that they should reduce *trans* fat consumption. FDA should adopt straightforward regulations which keep this message loud and clear.

Sincerely,



Peter J. Kadzik

Charles L. Miller Jr.

Doreen L. Manchester