



DEC 19 2003

Dr. Michael F. Jacobson
Executive Director
Center for Science in the Public Interest
Suite 300
1875 Connecticut Avenue, N.W.
Washington, D.C. 2000-6709

Re: Docket No. 94P-0036

Dear Dr. Jacobson:

This letter responds to your citizen petition dated February 14, 1994, requesting that the Food and Drug Administration (FDA) require the mandatory labeling of *trans* fatty acids and limit claims made for foods containing significant levels of *trans* fatty acids. In addition, this letter responds to your letter of July 13, 1998, which you amended your petition to suggest two alternatives for labeling *trans* fatty acids on the Nutrition Facts panel. In your petition, you stated that an increasing body of evidence suggests that dietary *trans* fatty acids raise low-density lipoprotein cholesterol (LDL-C) levels, thereby increasing the risk of coronary heart disease (CHD). To support the scientific basis of your petition, you submitted copies of scientific studies on the health effects of *trans* fat consumption. You stated that the 1993 final rule, entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label," which prescribes how nutrition labeling is to be provided on foods that are regulated by the agency, does not adequately reflect the effect of dietary *trans* fatty acids on CHD. You also stated that label values for saturated fat underestimate the total amount of "heart-unhealthy" fats because *trans* fatty acids are not declared. Therefore, you specifically requested that FDA: 1) amend its regulations in Title 21 of the Code of Federal Regulations (21 CFR 101.9(c)(2)(i)) to require the definition for saturated fat to read "the sum of all fatty acids containing no double bonds or containing double bonds in a *trans* configuration"; 2) base the requirements for nutrient content claims in § 101.62(c) (fatty acid content claims), § 101.62(d) (cholesterol content claims), and § 101.62(e) ("lean" and "extra lean" claims) on the combined level of saturated and *trans* fatty acids; 3) base the disqualification and disclosure levels for health and nutrient content claims on the combined levels of saturated and *trans* fats; 4) limit "vegetable oil" claims to foods

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that are low in saturated and *trans* fats combined; and 5) require that “partially hydrogenated” fat be listed on food labels as “partially saturated” fat.

You also provided in your July amendment two alternatives for labeling *trans* fat that would maintain the definition of saturated fat. Specifically, you proposed that FDA could either 1) disclose the sum of *trans* and saturated fats next to the term “saturated fat*” with an asterisk at the bottom of the label that states “contains ___ grams of *trans* fat,” or 2) disclose the sum of *trans* and saturated fats next to the term “saturated + *trans* fat” only when *trans* fat was present. You explained that the first option would allow the declaration of *trans* fat to be voluntary in foods that have levels of *trans* fat that are not detectable by standard laboratory analysis.

Following a careful review of the scientific evidence submitted in your petition, the scientific evidence that became available since 1994, and comments received in response to the petition, we published in the November 17, 1999 Federal Register a proposed rule (in partial response to your petition) entitled “Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims” (November 1999 proposal) (64 FR 62746). In that document, we proposed to amend the nutrition labeling regulations to require that the amount of *trans* fat in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fat with a footnote indicating the amount of *trans* fat in a serving of the product when the product contains 0.5 or more grams *trans* fat per serving. Interested persons were given until February 15, 2000 to comment on the proposal.

In response to several comments to the November 1999 proposal requesting that the final rule define the nutrient content claims “reduced *trans* fat” and “reduced saturated and *trans* fat,” we reopened the comment period for the November 1999 proposal (65 FR 75887; December 5, 2000) until January 19, 2001. In that document we stated that we would consider only comments that addressed “reduced *trans* fat” and “reduced saturated and *trans* fat” claims.

Subsequent to the December 5, 2000, Federal Register notice, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids” (the IOM/NAS report)¹. The IOM/NAS report recommended that “*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.” This recommendation is consistent with the conclusions in two other scientific reports, which became available subsequent to the November 1999 proposal, i.e., the Dietary Guidelines for Americans, 2000² and guidelines from the National Cholesterol

¹ IOM/NAS, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids*, National Academy Press, Washington, DC, 2002 (Internet address: <http://www.nap.edu>).

² U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. 5th ed. Washington DC; Home and Garden Bulletin No. 232, 2000.

Education Program (NCEP)³. Although the IOM/NAS report underscored the relationship between the intake of *trans* fat and the increased risk for heart disease, and emphasized that consumers need to limit *trans* fat in their diets, it did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that we believe was sufficient to support establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV for *trans* fat. However, in an effort to provide consumers with label information that will enable them to understand the quantitative declaration of *trans* fat in context of a total daily diet, we again reopened the comment period of the November 1999 proposal until December 16, 2002 (67 FR 69171; November 15, 2002). In that document, we also proposed to require an asterisk (or other symbol) in the %DV column for *trans* fat, when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box that is followed by the statement "Intake of *trans* fat should be as low as possible."

In accordance with 21 CFR 10.30(e)(3), we are granting in part and denying in part your petition. This decision is based on our review of the scientific evidence published since the November 1999 proposed rule, and in response to the recommendations of the IOM/NAS and other authoritative groups. We also considered comments received in response to the November 1999 proposed rule and the two notices reopening the comment period on the proposed rule. An explanation of our decision follows.

1. Petition to require the mandatory labeling of trans fat because of public health concern related to increased risk of coronary heart disease related to trans fat consumption.

We granted this request in the July 11, 2003 Federal Register (the July 2003 final rule) (68 FR 41434) where we amended 21 CFR 101.9 and 101.36 to require the mandatory labeling of *trans* fat on nutrition labels to help consumers maintain healthy dietary practices. In reaching this decision, based on an independent evaluation of studies cited in your submission as well as recent studies in humans identified by a supplemental literature search, we concluded that controlled intervention studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing *trans* fats, like diets containing saturated fats, result in increased serum LDL-C compared with the consumption of diets containing cis-monounsaturated or cis-polyunsaturated fat sources. We also noted that several authoritative guidelines^{2,3} and the IOM¹ recommend that Americans consume diets low in *trans* fat because of its association with increased risk of CHD.

³ Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Chapter II. "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," 2001. (internet address: <http://www.NHLBI.nih.gov>)

2. Request to amend 21 CFR 101.9(c)(2)(i) to require the definition for saturated fat to read "the sum of all fatty acids containing no double bonds or containing double bonds in a trans configuration and either 1) disclose the sum of trans and saturated fats next to the term "saturated fat*" with an asterisk at the bottom of the label that states "contains ___ grams of trans fat," or 2) disclose the sum of trans and saturated fats next to the term "saturated + trans fat" only when trans was present.

We are denying the request to revise the definition of saturated fat in § 101.9(c)(2)(i) to include *trans* fat. As discussed in the November 1999 proposal, amending the regulatory definition of saturated fat would be scientifically inaccurate because *trans* fatty acids are not saturated, i.e., they contain double bonds. Current regulations define saturated fatty acids as "the sum of all fatty acids containing no double bonds" (see § 101.9(c)(2)(i) and 64 FR at 62755). Comments received in response to the November 1999 proposal strongly supported our proposal not to amend the definition of saturated fat to include *trans* fatty acids. Therefore, we finalized the definition for *trans* fat as "unsaturated fatty acids that contain one or more isolated (i.e., non-conjugated) double bonds in a *trans* configuration" in the July 2003 final regulation (68 FR 41434 at 41461-62).

We are also denying your request to combine saturated fatty acids and *trans* fatty acids into one numeric value. As you are aware, although we tentatively concluded in the November 1999 proposal that combining the two amounts under "saturated fat" with a footnote stating "Includes ___g *trans* fat" seemed to be the more effective way of informing consumers of the *trans* fatty acid content of food, we recognized that it may confuse consumers and lead some to misclassify *trans* fatty acids as saturated fats (see 64 FR at 62755). In fact, comments to the November 1999 proposal expressed strong opposition to combining the two amounts. Some argued that this approach was scientifically inaccurate and misleading because *trans* and saturated fats are chemically, functionally, and physiologically different (68 FR at 41452). Other opposing comments discussed the strength of the scientific basis for the rule; the relevance of amounts of *trans* fat consumed in intervention studies to usual conditions of use in the United States; whether, on a gram-for-gram basis, *trans* fat have an effect on LDL-C and CHD risk equivalent to, greater than, or less than saturated fat; and the importance of other adverse effects of *trans* fat in addition to the effects on LDL-C (68 FR at 41452-41453). Some comments suggested that because of these scientific issues that differentiate saturated and *trans* fats, *trans* fat should not be associated with saturated fat in the nutrition label. Accordingly, we withdrew this option in the July 2003 final rule (68 FR at 41453).

Instead, we were persuaded by comments that the most appropriate format for providing information on *trans* fat content is to declare *trans* fat on a separate line listed beneath saturated fat (68 FR at 41457). Therefore, we finalized this option and revised § 101.9(c) by adding paragraph § 101.9(c)(2)(ii) to require the quantitative declaration of *trans* fat in the Nutrition Facts panel with the listing of *trans* fat on a separate line under the statement for saturated fat (68 FR at 41457). We were also persuaded that there is insufficient scientific basis at this time for combining *trans* and saturated fats when

calculating the percent Daily Value (%DV) and inasmuch as the decision was made to list *trans* on a separate line, the issue of combining the two to calculate %DV is moot.

3. Petition to base the requirements for nutrient content claims in § 101.62(c) (fatty acid content claims), § 101.62(d) (cholesterol content claims), and § 101.62(e) ("lean" and "extra lean" claims) on the combined level of saturated and trans fatty acids, and to base the disqualification and disclosure levels for health and nutrient content claims on the combined levels of saturated and trans fats.

We are denying this request. As discussed in the July 2003 final rule, in the absence of an appropriate reference value, we have withdrawn those sections of the November 1999 proposal pertaining to the establishment of nutrient content claims for *trans* fat and limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. As discussed in the July 2003 final rule, we rely extensively on reports from IOM/NAS in developing the current Reference Daily Intakes and DRVs. However, the IOM/NAS report¹ does not contain quantitative recommendations for *trans* fat that could be the basis for establishing a DRV (68 FR at 41456-57). Accordingly, we did not establish a DRV for *trans* fat, establish new or amend existing nutrient content claims, or amend disclosure and disqualifying levels in the *trans* fat final rule. We continue to have an interest in doing so. To this end, we also published on July 11, 2003, an advance notice of proposed rulemaking (ANPRM) that solicits information and data that potentially could lead to further rulemaking on such claims as well as disclosure and disqualifying levels (68 FR 41507).

4. Request to limit "vegetable oil" claims to foods that are low in saturated and trans fats combined.

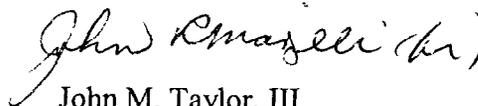
We are denying this request. As discussed in the November 1999 proposal (64 FR at 62762), we tentatively concluded that this request was being addressed by the action to limit the amount of *trans* fat in foods bearing "low in saturated fat" claims. However, as discussed in response to #3 above, the agency is not defining nutrient content claims for *trans* fat at this time. Thus, the agency is not defining what may be an implied claim for "low *trans* fat" with respect to a vegetable oil labeled as "100 percent vegetable oil." We continue to have an interest in establishing nutrient content claims for *trans* fat and for including *trans* fat limits in claims that currently have limits on saturated fat. As previously noted, we published an ANPRM in conjunction with the July 2003 final rule that could lead to further rulemaking pertaining to limits on the amount of *trans* fat in claims relating to saturated fat when the science on *trans* fat has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims (68 FR 41507).

5. Request to require that "partially hydrogenated" fat be listed on food labels as "partially saturated" fat.

We are denying this request. As noted in the November 1999 proposal, the agency has previously considered this issue and stated that we continue to believe that use of the terms "saturated" and "partially saturated" to describe fats and oils processed in a certain way may mislead consumers to equate fats and oils that, in fact, differ substantially in their content of "heart-healthy" fats (64 FR at 62762). This misperception could cause consumers to avoid a processed oil, which would be required to be identified as "partially saturated," and instead choose an unprocessed fat or oil, which would cause no designation even though it may contain more saturated fatty acids than the combined amount of saturated fatty acids and *trans* fatty acids in another product (64 FR at 62762). As discussed in the proposal, the purpose of the requirement (§ 101.4(b)(14)) for the common or usual name of an oil ingredient is to distinguish unprocessed from processed oils and fats. The term "hydrogenated" more accurately makes this distinction because "saturated" describes a chemical characteristic of a fatty acid (64 FR at 62762). No comments to the proposal were received on this issue; therefore, we are not persuaded to change this conclusion.

In conclusion, we find, based on our review of the authoritative reports by public health groups, including those of the Federal government, and on a review of results of the available scientific evidence, that *trans* fatty acids are associated with an increased risk of CHD, and therefore, it is appropriate to require *trans* fatty acids on the Nutrition Facts label of foods, including dietary supplements, to assist consumers in making healthy dietary choices. We have published in the July 11, 2003 Federal Register a final rule that codifies the mandatory labeling of this nutrient. However, in the absence of a DRV for *trans* fat, we are denying your requests to amend the definition of nutrient content claims to include *trans* fat with saturated fat; to base the disqualification and disclosure levels for health and nutrient content claims on the combined levels of saturated and *trans* fat; to limit vegetable oil claims to foods low in saturated and *trans* fats; and to require partially hydrogenated fat to be listed as "partially saturated" fat. We plan to continue to evaluate the emerging science and revisit the issue of establishing threshold levels of *trans* fat in nutrient content claims and health claims, and disclosure and disqualifying levels for *trans* fat once the scientific evidence has evolved to a point at which the agency believes the scientific evidence would support such a rulemaking.

Sincerely yours,



John M. Taylor, III
Associate Commissioner
for Regulatory Affairs